United States Court of Appeals
for the
District of Columbia Circuit

TRANSCRIPT OF RECORD

JOINT APPENDIX

United States Court of Appeals
FOR THE DISTRICT OF COLUMBIA CIRCUIT

793

No. 16,862

THE COMMONWEALTH ENGINEERING COMPANY OF
OHIO AND CARL BERGER,
Appellants

vs.

DAVID L. LADD, COMMISSIONER OF PATENTS,
Appellee

**Appeal from the United States District Court
for the District of Columbia**

United States Court of Appeals
for the District of Columbia Circuit

FILED MAR 26 1962

Joseph W. Stewart

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INDEX TO JOINT APPENDIX

C.A. 2997-59

PAGE

Docket Entries 1

Bill of Complaint 4

Answer 10

Transcript of Proceedings in District Court 17

Patent application of Carl Berger Ser. No. 370,533 87

Drawing illustrating apparatus for Carrying out of Process of the Invention 95

Patent and Publications cited by Patent Office 96

Plaintiff's Exhibits .... 102 and 112

Blood Cells Preservation (Publication) 116

Affidavits

Harry A. Toulmin, Jr. 109-110
Leo Novak 117

Process Claims of Appellant 118-119

Decision of Board of Appeals Patent Office 127

Decision on Petition for Reconsideration 138

Findings of Fact 80

Opinion of The District Court 74

Judgment 84

Notice of Appeal 84

United States Court of Appeals

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THE COMMONWEALTH ENGINEERING COMPANY OF
OHIO AND CARL BERGER,
Appellants

vs.

DAVID L. LADD, COMMISSIONER OF PATENTS,
Appellee

**Appeal from the United States District Court
for the District of Columbia**

JOINT APPENDIX

IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF COLUMBIA

C.A. 2997-1959

The Commonwealth Engineering Company
of Ohio and Carl Berger,
1771 Springfield Street, Dayton, Ohio
Plaintiffs

vs.

Robert C. Watson,
Commissioner of Patents,
Defendant

DOCKET ENTRIES

1959

October 23—$10.00 pd. Bill of Complaint & Fee

October 23—Summons (3). Copies (3), Complaint issued U.S. Atty. Ser. 10-26; Atty. Gen. ser. 10-30

December 17—Answer of deft. to complt. c/m 12-17-59. App. C. W. Moore. Filed

December 17—Calendared (N)

1961

May 4—Consent order substitution David L. Ladd, Commissioner of Patents, as party deft. in place of Robert C. Watson. (N) Youngdahl, J.

October 25—Trial of pltfs.

October 30—Hearing begun and continued to 10:00 AM October 31, 1961. Holtzoff, J.
(Rep. Nevitt)

October 31—Hearing resumed; finding for the deft. (Order to be presented) Holtzoff, J.

1961

November 22—Memorandum of Opinion dismissing complaint (N) Holtzoff, J.

November 28—Transcript of proceedings of October 30. 31, 1961

Vol. I, pp. 1-94
Reporter: Gerald Nevitt
(Court's copy) filed

November 30—Findings of Fact and Conclusion of Law (N) Holtzoff, J.

November 30—Order dismissing complaint with costs vs. pltf. (N) Holtzoff, J.

1962

January 11—Notice of appeal of pltfs.; deposit by Toulmin $5.00 (copy mailed to C. W. Moore). Filed

January 11—Transcript of proceedings 10-30-61 and 10-31-61

Vol I, pp. 1-94. Filed
(Reporter G. Nevitt)

January 16—Bond of pltf. with Hartford Accident and Indemnity Co. in the sum of $250.00; copy of power of Atty. attached (fiat). Sirica, J.

February 14—Record on Appeal delivered to USCA; deposit by Bickel of 80¢

February 14—Receipt from USCA for original Record.

BILL OF COMPLAINT FOR THE ISSUANCE OF A PATENT

To the Honorable Judges of the District Court of the United States for the District of Columbia:

Plaintiffs bring this cause of action and state as follows:

1. Plaintiff, the Commonwealth Engineering Company of Ohio is a corporation organized and existing under the laws of the State of Ohio, having a place of business at 1771 Springfield Street, Dayton, Ohio; and Plaintiff Carl Berger is a citizen of the United States, residing at 24320 Chippewa Street, Detroit, Michigan, and Plaintiffs bring this suit jointly.

2. The Defendant, Robert C. Watson, is Commissioner of Patents of the United States, having his official residence in the District of Columbia, and is sued in his official capacity as said Commissioner of Patents of the United States.

3. This suit arises under the patent laws of the United States and this Bill is filed in accordance with the provisions of Sec. 35 U.S.C. 145.

4. That Carl Berger, one of the Plaintiffs, prior to July 27, 1953, was the true, original and first inventor of the improvements in "Reconstitution of Frozen Biological Cellular Material", which was not known or used by others in this country before his invention or discovery thereof and were not patented or described in any printed publication in this or any foreign country before his invention or discovery thereof, or more than one year prior to this application for a patent hereinafter referred to, and were not in public use or on sale in this country for more than one year prior to said application, were not abandoned and were not patented in any foreign country on an application filed by either of said Plaintiffs or their legal representatives or assigns more than twelve months prior to the filing of said application in the United States.

5. That Plaintiff Carl Berger, being entitled to Letters Patent of the United States for "Reconstitution of Frozen Biological Cellular Material" under the provisions of the Statutes of the United States and in accordance with the Rules of Practice of the United States Patent Office, filed an application for Letters Patent in due and proper form with the Defendant, or his predecessor in office, as Commissioner of Patents for said improvements, said application complied with the Statutes and Rules in such cases made and provided and was filed in the United States Patent Office on July 27, 1953, and was given Serial No. 370,533, all as will more fully and at large appear by said application or a duly certified copy thereof and the proceedings relating thereto had in the Patent Office, here in Court to be produced by the Plaintiffs.

6. That said Plaintiff, Carl Berger, by a proper instrument in writing, executed by him and recorded in the records of the Transfers of Patents in the United States Patent Office, sold, assigned and transferred to The Commonwealth Engineering Company of Ohio, the other Plaintiff, herein, the entire right, title and interest in and to the invention disclosed in said application Serial No. 370,533, and in and to the Letters Patent expected to issue thereon, whereby said The Commonwealth Engineering Company of Ohio became invested with and now owns the entire right, title and interest in and to said invention and the Letters Patent to issue therefor, as will more fully and at large appear by said assignment or a duly certified copy thereof in Court to be produced.

7. That said application has been duly prosecuted in accordance with the laws of the United States and the Rules of Practice of the United States Patent Office.

8. That a patent on said application, including and embodying Claims 17, 24, 25 and 26, being all of the claims retained in this case, has been refused by the Commissioner of Patents, the Defendant herein.

9. That said application was examined by the Primary Examiner in the United States Patent Office who finally rejected claims 3, 6, 9, 10, 12, 14, 15 and 17 as failing to properly define the invention and, as to claims 3 and 6, alleged that they were incomplete and that they did not set forth the differential temperatures of the channel; the Examiner rejecting claims 3, 9, 10 and 12 as being too broad. The claims were further rejected on the grounds that they lack utility because there was asserted to have no showing of record to the effect that the high temperatures used in applicant's method would not cause denaturation of the blood proteins due to localized heating.

10. Applicant, in response to the final rejection made by the Examiner and endeavoring to overcome the rejection made that the claims did not properly define the invention, presented claims 20, 21, 22 and 23 in lieu of in lieu of claims 3, 6, 9, 10, 12, 14 and 15, and requested reconsideration of these claims and pointed out that the literature supported applicant's teaching that the process of treating frozen biological cells, such as blood, as disclosed by applicant, would produce a blood having the utility described in the application and that further evidence was not believed required.

11. The Examiner again rejected the claims for lack of showing with respect to utility and that claims 22 and 23 were improper with respect to certain phraseology of the claims.

12. In response to this action of the Examiner, applicant presented claims 24, 25 and 26 and withdrew claims 3, 6, 9, 10, 12, 14 and 15 without prejudice. Applicant, in addition, presented an affidavit of Harry A. Toulmin, Jr., setting forth the history of the research and development work leading to the invention and setting forth the utility of the invention, particularly with respect to obtaining reconstituted frozen blood cells quickly and without injury to the cells.

13. The Examiner responded with approval for entry of claims 24, 25 and 26 and retention of claim 17 for appeal purposes, but again rejected all of the claims for lack of utility, alleging that applicant's method of using high temperatures to thaw blood cells must be shown to not cause denaturation of the blood cells.

14. Applicant filed an affidavit of Leo J. Novak, Vice President in Charge of Research and Development for the Defendant company, in which he corroborated the statements made in the affidavit of Harry A. Toulmin, Jr., and stating that frozen blood cells reconstituted in accordance with applicant's invention have been used and have been found to be satisfactory and that the process for reconstituting frozen blood cells as set forth in the claims produced a reconstituted blood cell product which can be used in like manner as frozen blood cells which have been slowly heated up in the conventional manner, and requested reconsideration and allowance in view of the showing of record.

15. That no prior art, as cited, is anticipatory of applicant's invention, the reference to:

> Tullis—Blood Cells and Plasma Proteins, 1953, Academic Press, NYC, pp. 207 and 208

being cited to show the test which the Examiner stated should be presented to establish utility in a case of this nature.

16. That the Plaintiffs are clearly entitled to the allowance of the claims retained of record and took an appeal to the Patent Office Board of Appeals on or about November 28, 1956 from the final rejection of all of the claims by the Primary Examiner, said claims reading as follows:

> 17. A process for the reconstitution of frozen blood cells which includes the steps of establishing a temperature gradient channel decreasing substan-

tially uniformly between 250°C and 50°C, flowing a stream of the cells under the influence of gravity alone through said temperature gradient channel being initially subjected to said temperature of 250°C to substantially thaw the cells in a time on the order of seconds, and collecting the cells after passing through said temperature gradient channel in an isotonic solution having substantially the same temperature as the thawed cells.

24. A process for the reconstitution of frozen blood cells which consists in passing the same through an enclosure having a temperature gradient from the entrance to the exit of between 1100°C and 250°C at said entrance and 37°C to 50°C at said exit, the temperature decreasing substantially uniformly therebetween, said blood cells entering and passing through said temperature gradient enclosure within approximately one to two seconds to thaw the same quickly, and thereafter collecting the resultant thawed cells in an isotonic liquid having substantially the same temperature as the thawed cells.

25. A process for the reconstitution of frozen blood cells which consists in propelling the same through an enclosure with inert gas, said enclosure having a temperature gradient from the entrance to the exit of between 1100°C and 250°C at said entrance and 37°C to 50°C at said exit, the temperature decreasing substantially uniformly therebetween, said blood cells entering and passing through said temperature gradient enclosure within a few seconds to thaw the same quickly, and thereafter collecting the resultant thawed cells in an isotonic liquid having substantially the same temperature as the thawed cells.

26. A process for the reconstitution of frozen blood cells which tend to cluster, said process comprising flowing the same through a heat gradient atmosphere which starts initially at a temperature of approximately 1100°C and decreases substantially uniformly to a temperature of approxi-

> mately 37°C, said cells being passed through said gradient atmosphere at a high rate of speed and on the order of from one to two seconds, and wherein a velocity is imparted to said cells by inert gas introduced into said gradient atmosphere, and collecting said blood cells after passing through said gradient atmosphere in an isotonic liquid, said liquid being at substantially the same temperature as the cells after passing through said gradient atmosphere.

17. Counsel for applicant on or about January 25. 1957 filed a Brief to the Board of Appeals and set out the reasons why the claims were believed to be patentable to applicant and requested that the Board of Appeals reexamine and reverse the Examiner's rejection of the claims.

18. On March 19, 1957, the Examiner filed his Answer to applicant's Brief, wherein he set forth his reasons why the rejection of the claims should be sustained by the Board of Appeals.

19. On or about March 27, 1957, applicant, through his counsel, filed a Reply Brief, wherein he set forth his reasons that the rejection of the claims by the Examiner was not supported in fact and should be sustained by the Board of Appeals.

20. After the filing of applicant's Briefs and a hearing had before the Board of Appeals, the Board affirmed the decision of the Examiner in a communication dated May 6, 1959. The Plaintiffs thereafter filed a Request for Reconsideration of the Decision by the Board of Appeals, giving reasons wherein the same was in error and not supported neither in fact nor in law.

21. That the Plaintiffs have taken no appeal to the United States Court of Customs and Patent Appeals from the aforesaid decisions of the Patent Office Board of Appeals and the Commissioner of Patents.

tially uniformly between 250°C and 50°C, flowing a stream of the cells under the influence of gravity alone through said temperature gradient channel being initially subjected to said temperature of 250°C to substantially thaw the cells in a time on the order of seconds, and collecting the cells after passing through said temperature gradient channel in an isotonic solution having substantially the same temperature as the thawed cells.

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25. A process for the reconstitution of frozen blood cells which consists in propelling the same through an enclosure with inert gas, said enclosure having a temperature gradient from the entrance to the exit of between 1100°C and 250°C at said entrance and 37°C to 50°C at said exit, the temperature decreasing substantially uniformly therebetween, said blood cells entering and passing through said temperature gradient enclosure within a few seconds to thaw the same quickly, and thereafter collecting the resultant thawed cells in an isotonic liquid having substantially the same temperature as the thawed cells.

26. A process for the reconstitution of frozen blood cells which tend to cluster, said process comprising flowing the same through a heat gradient atmosphere which starts initially at a temperature of approximately 1100°C and decreases substantially uniformly to a temperature of approxi-

> mately 37°C, said cells being passed through said gradient atmosphere at a high rate of speed and on the order of from one to two seconds, and wherein a velocity is imparted to said cells by inert gas introduced into said gradient atmosphere, and collecting said blood cells after passing through said gradient atmosphere in an isotonic liquid, said liquid being at substantially the same temperature as the cells after passing through said gradient atmosphere.

17. Counsel for applicant on or about January 25, 1957 filed a Brief to the Board of Appeals and set out the reasons why the claims were believed to be patentable to applicant and requested that the Board of Appeals reexamine and reverse the Examiner's rejection of the claims.

18. On March 19, 1957, the Examiner filed his Answer to applicant's Brief, wherein he set forth his reasons why the rejection of the claims should be sustained by the Board of Appeals.

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20. After the filing of applicant's Briefs and a hearing had before the Board of Appeals, the Board affirmed the decision of the Examiner in a communication dated May 6, 1959. The Plaintiffs thereafter filed a Request for Reconsideration of the Decision by the Board of Appeals, giving reasons wherein the same was in error and not supported neither in fact nor in law.

21. That the Plaintiffs have taken no appeal to the United States Court of Customs and Patent Appeals from the aforesaid decisions of the Patent Office Board of Appeals and the Commissioner of Patents.

22. Wherefore Plaintiffs bring this Bill of Complaint under and in accordance with the provisions of the Statutes (35 U. S. Code, Section 145) in such cases made and provided, and pray:

(a) That this Honorable Court may adjudge that the Plaintiffs, the Commonwealth Engineering Company of Ohio and Carl Berger, are entitled according to the law to receive Letters Patent of the United States for said invention set forth in the aforesaid claims, 17, 24, 25 and 26, of said application of Carl Berger, Serial No. 370,533;

(b) That this Honorable Court may decree that the Commissioner of Patents be directed to allow the aforesaid claims of said application and direct the Commissioner to issue a patent to applicant; and

(c) For such other and further relief in the premises as the nature of the case may require and as to the Honorable Court shall seem meet and proper.

THE COMMONWEALTH ENGINEERING COMPANY OF OHIO

TOULMIN & TOULMIN

By

Harry A. Toulmin, Jr.
Folsom E. Drummond
Of Counsel

Washington, D. C.

* * * *

ANSWER TO THE COMPLAINT

To the Honorable the Judges of the United States District Court for the District of Columbia

1. The defendant asserts that he is without knowledge or information sufficient to form a belief as to the truth of the allegation that plaintiff, Carl Berger, resides at 24320 Chippewa Street, Detroit, Michigan. The defendant admits the remaining allegations of paragraph 1 of the complaint.

2, 3. The defendant admits the allegations of paragraphs 2 and 3 of the complaint.

4. The defendant asserts that he is without knowledge of information sufficient to form a belief as to the truth of the allegations of paragraph 4 of the complaint.

5. The defendant denies that plaintiff, Carl Berger, is entitled to Letters Patent of the United States for "Reconstitution of Frozen Biological Cellular Material" under the provisions of the Statutes of the United States and in accordance with the Rules of Practice of the United States Patent Office. The defendant admits that plaintiff, Carl Berger, filed an application for Letters Patent in due and proper form with him as Commissioner of Patents for said improvements. The defendant denies that said application complied with the Statutes and Rules in such cases made and provided. The defendant admits that said application was filed in the United States Patent Office on July 27, 1953, and was given Serial No. 370,533.

6, 7, 8, 9. The defendant admits the allegations of paragraphs 6, 7, 8, and 9 of the complaint.

10. The defendant admits that applicant presented claims 21, 22, and 23 in lieu of claims 3, 6, 9, 10, 12, 14, and 15. The defendant denies that applicant so presented

claim 20. The defendant also denies that claims 20, 21, 22, and 23 were presented in response to the final rejection made by the Examiner. The defendant asserts that he is without knowledge or information sufficient to form a belief as to the truth of the allegation that applicant endeavored to overcome the rejection made that the claims did not properly define the invention. The defendant denies the remaining allegations of paragraph 10 of the complaint.

11. The defendant denies the allegations of paragraph 11 of the complaint.

12. The defendant admits that applicant presented claims 24, 25, and 26 and withdrew claims 3, 6, 9, 10, 12, 14, and 15 without prejudice and that applicant, in addition, presented an affidavit of Harry A. Toulmin, Jr., setting forth the history of the research and development work leading to the invention and setting forth the utility of the invention, particularly with respect to obtaining reconstituted frozen blood cells quickly and without injury to the cells, but the defendant otherwise denies the allegations of paragraph 12 of the complaint.

13. Except for admitting that the Examiner approved entry of claims 24, 25, and 26 for appeal purposes, the defendant denies the allegations of paragraph 13 of the complaint.

14. The defendant admits that applicant filed an affidavit of Leo J. Novak, Vice President in Charge of Research and Development for The Commonwealth Engineering Company of Ohio, in which he stated that frozen blood cells reconstituted in accordance with applicant's invention have been used and have been found to be satisfactory, and that applicant requested allowance, but the defendant otherwise denies the allegations of paragraph 14 of the complaint.

15. The defendant admits that no prior art, as cited, is anticipatory of applicant's invention, but the defendant otherwise denies the allegations of paragraph 15 of the complaint.

16. The defendant admits that plaintiff, Carl Berger, took an appeal to the Patent Office Board of Appeals on November 28, 1956, from the final rejection of claims 3, 6, 9, 10, 12, 14, 15, and 17 by the Primary Examiner, but the defendant otherwise denies the allegations of paragraph 16 of the complaint.

17. The defendant admits that counsel for applicant about January 25, 1957, filed a Brief to the Board of Appeals and set out the reasons why the claims were believed to be patentable to applicant, but the defendant otherwise denies the allegations of paragraph 17 of the complaint.

18. The defendant admits the allegations of paragraph 18 of the complaint.

19. The defendant admits that on March 27, 1957, applicant, through his counsel, filed a Reply Brief, but the defendant otherwise denies the allegations of paragraph 19 of the complaint.

20. The defendant admits that after the filing of applicant's Briefs and a hearing had before the Board of Appeals, the Board affirmed the decision of the Examiner in a communication dated May 6, 1959, and that the plaintiff, Carl Berger, thereafter filed a Request for Reconsideration of the Decision by the Board of Appeals, but the defendant otherwise denies the allegations of paragraph 20 of the complaint.

21. Except for denying that there is an aforesaid decision of the Commissioner of Patents, the defendant admits the allegations of paragraph 21 of the complaint.

22. Paragraph 22 of the complaint, being in the form of prayers, no answer is made thereto.

FURTHER ANSWERING, the defendant asserts that the plaintiffs are not entitled to a patent containing any of claims 17, 24, 25, and 26 of the application involved in this civil action, for the reasons given and in view of the reference cited in the Examiner's answer and the decisions of the Board of Appeals in that application. Profert hereby is made of copies of the said answer, decisions and reference.

Respectfully submitted,

/s/ C. W. Moore
Solicitor
United States Patent Office
Attorney for Defendant

December 17, 1959

I hereby certify that two copies of the foregoing ANSWER TO THE COMPLAINT were mailed today to the attorney for the plaintiffs, Toulmin & Toulmin, Pennsylvania Bldg., Washington, D. C.

/s/ C. W. Moore
Solicitor

IN THE
UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

Civil Action No. 2997-59

THE COMMONWEALTH ENGINEERING COMPANY
OF OHIO, and
CARL BERGER,
Plaintiffs

vs.

DAVID L. LADD,
Commissioner of Patents,
Defendant

CERTIFIED RECORD OF OFFICIAL COURT REPORTER

Proceedings Before Judge Holtzoff
October 30, 31, 1961

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Prepared for Defendant

GERALD NEVITT
Official Court Reporter

United States Court House Washington 1, D. C.
Telephone: STerling 3-5700

UNITED STATES DISTRICT COURT FOR THE DISTRICT OF COLUMBIA

Civil Action No. 2997-59

The Commonwealth Engineering Company
of Ohio, and
Carl Berger,
Plaintiffs

vs.

David L. Ladd,
Commissioner of Patents,
Defendant

Washington, D. C.
October 30, 1961.

The above-captioned cause came on for trial before the HONORABLE ALEXANDER HOLTZOFF, Judge, United States District Court for the District of Columbia.

APPEARANCES:

On behalf of the Plaintiffs:

DWIGHT F. BICKEL, ESQ.
FOLSOM E. DRUMMOND, ESQ.

On behalf of the Defendant:

JACK E. ARMORE, ESQ.
Patent Office.

2 • • • •

3 PROCEEDINGS

THE DEPUTY CLERK: Commonwealth Engineering Company of Ohio vs. Watson.

MR. DRUMMOND: Your Honor, my name is Folsom E. Drummond. I am a member of the Bar of the District and counsel for the plaintiff. At this time, your

Honor, I would like to move the admission of Mr. D. F. Bickel, who is to argue the case for plaintiff. He is a member of the Bar of the State of Illinois and the Bar of the State of Ohio.

THE COURT: Where is his office?

MR. DRUMMOND: He is in Ohio, Dayton, Ohio.

THE COURT: He is a member of the Bar of the State of Illinois?

MR. DRUMMOND: Illinois Bar.

THE COURT: But his office is in Ohio?

MR. BICKEL: I just joined the firm of Toulmin and Toulmin, your Honor.

THE COURT: Mr. Bickel, you may be admitted pro hac vice. You may proceed.

MR. BICKEL: Your Honor, would the Court desire a short opening statement on the part of the plaintiff?

THE COURT: Yes; in every case.

You may proceed.

4 OPENING STATEMENT BY COUNSEL ON BEHALF OF PLAINTIFFS

MR. BICKEL: Your Honor, this case involves an appeal from a decision of the Patent Office Board of Appeals rejecting plaintiffs' application for a patent.

The invention involved in the case is for a process for a rapid thawing and reconstituting of frozen—

THE COURT: A process for what?

MR. BICKEL: The invention involves a process for the rapid thawing and melting—

THE COURT: Rapid what?

MR. BICKEL: Thawing of frozen red blood cells. Perhaps before discussing—

THE COURT: Let me see if I understand it correctly. You say thawing of red blood cells?

MR. BICKEL: Frozen red blood cells.

THE COURT: In connection with blood transfusions?

MR. BICKEL: That, your Honor, is one of the issues in the case. Definitely this is a step toward developing a process whereby stored blood may be made immediately available for transfusion purposes.

THE COURT: I say, it is in connection with blood transfusions?

MR. BICKEL: One of the issues in the case,
5 your Honor, will concern the matters of utility and usefulness.

THE COURT: I know, but for what purpose is this to be used, for blood transfusions?

MR. BICKEL: It may be used for laboratory samples of blood and, with refinements, may be used for transfusion purposes.

THE COURT: I see.

MR. BICKEL: Perhaps an introductory remark about the need for this type of device would be helpful to the Court.

Blood stored in its liquid state tends to deteriorate rapidly and, as a result, the art has been engaged for some years now in finding a method whereby blood may be stored for a considerable length of time without deteriorating. The method which has been developed is a quick freezing method, whereby the blood will remain in a usable state for a considerable length of time. However, the prior methods of reconstituting this frozen blood into a usable liquid state again, have involved a slow warming process whereby it gradually came back up to room temperature. This slow process is what the invention here ensued attempts to avoid; and, as a matter of fact, we believe the evidence will show you that it does avoid it.

THE COURT: You mean this is a quick process?

MR. BICKEL: This is a quick process for bring-
6 ing that frozen blood back into a liquid state.

THE COURT: I see.

MR. BICKEL: The procedure before the Patent Office I might discuss because it helps to show the Court that there really is but one issue remaining in this case. There is no question raised in the Patent Office as to anticipation, no question has been raised as to any matter whatsoever except the question of utility. So, the sole discussion here concerns whether or not the requirements of Section 101 of 35 U.S.C. have been met in that the invention be useful within the meaning of the patent law.

Perhaps we might even more clearly define the particular issue here because utility alone does not really explain the grounds of the Patent Office rejection. Specifically, the Patent Office rejected for the ground that it was inoperable. In other words, it would not work, and therefore they said it had no utility.

THE COURT: Well, the two things are interchangeable.

MR. BICKEL: They are interchangeable, your Honor, but it is actually more or less a specific phase of the utility question that we are here concerned with.

We believe that there are actually five matters which bear upon the question and show that the plaintiffs have
made a satisfactory showing in the Patent Office
7 for the granting of a patent. First of all, there
is some utility to this. The Patent Office—perhaps
I should have explained this—the Patent Office has required tests to be submitted showing that this process produces an end result suitable for human transfusion. The application at no point claims or states that this apparatus produces a thawed blood product suitable for human transfusion purposes.

THE COURT: The application says what?

MR. BICKEL: It does not claim that the thawed or melted blood cells are suitable for human transfusion purposes. As a matter of fact, we plan to introduce testimony to show standard laboratory uses for this blood which would be very helpful and would not at all require human transfusion.

We feel that the Patent Office, in requiring a showing of clinical tests of human transfusion, has extended its authority beyond what it should have.

THE COURT: Tell me this, Mr. Bickel, what are the laboratory uses of blood besides medical uses?

MR. BICKEL: There are standard—there are tests which are run. Frankly, your Honor, the particular tests, I don't know as I could even pronounce the words. Our expert witness will go into these in some detail for the Court.

THE COURT: I am not asking you to testify, I am asking you to answer my question. What are the uses?

8 MR. BICKEL: Laboratory tests. For example, in certain syphilis tests which are run it is necessary to have a standard blood sample of normal human blood with which to compare the patient's blood; and we intend to show that this process would be useful for providing those samples.

THE COURT: In any event, it is a medical use?

MR. BICKEL: It is used in the general medical field, yes, your Honor, definitely.

THE COURT: I am rather curious, why should an engineering company go into the medical field?

MR. BICKEL: That "Engineering Company" doesn't really describe the scope of the plaintiff's activities. The plaintiff company does considerable work for a pharmaceutical company, for example, in doing some of its research.

THE COURT: I see.

MR. BICKEL: However, I don't want to mislead the Court. This particular patent is not owned by the pharmaceutical company, but Commonwealth itself has engaged at some length in this general field.

THE COURT: Has this invention been submitted to the Food and Drug Administration?

MR. BICKEL: No, your Honor. Your Honor, you asked the question whether or not it had been submitted

to the Food and Drug Administration. The answer
9 is no. No new product is created by this invention.

This is a process for simply changing frozen blood to liquid blood.

THE COURT: I see.

MR. BICKEL: No new matter or new form of matter is created.

THE COURT: I see.

MR. BICKEL: We intend to show these uses that I mentioned before.

We further want to point out to the Court in our argument that the law does not require that a device be perfectly operable in order to be patentable.

THE COURT: I know, but when you enter the medical field you are dealing with human life.

MR. BICKEL: That is correct, your Honor.

THE COURT: Sometimes a slight imperfection might kill some person.

MR. BICKEL: That certainly is true.

THE COURT: Or adversely affect his health.

MR. BICKEL: I think perhaps the whole case here involves this question. You see, no claim is made that this is to be used on human beings and, as a matter of fact, there are uses for it other than treating human beings, and that is one of the very important points in this case, I believe, your Honor.

THE COURT: Do you advertise this product,
10 or this process? In other words, you are telling
me that it does not have to be used on human beings. In the literature concerning this process are you going to say please do not use it on human beings?

MR. BICKEL: Your Honor, I think that, first of all, I can't speak for the literature on the process because certainly it is not being sold at the present time. It is a step which, with further refinement, could be so produced and sold for use in that purpose. However, the showing that we intend to make in the court today, through our expert witness, is that indeed this process would produce a result which would not be harmful; that the harmful effects which the Patent Office mentioned—and they only mentioned one: they thought perhaps the blood cells would be scorched—that this will not occur. In other words, we have here, and we feel this is an essential distinction in the case, we have here not a new medicine. There is no new medicine here. There is no new chemical compound. This is a process claim. We are dealing with a known matter.

THE COURT: Then what does the process consist of?

MR. BICKEL: Thawing in a quick manner red blood cells.

THE COURT: But what is there patentable about it? What is the patentable feature?

MR. BICKEL: The patentable feature, your
11 Honor, is that no one before—and the Patent Office has not questioned this in any manner—that no one before had invented or disclosed a device which would quickly thraw the frozen blood cells.

THE COURT: But you say this is a process, this is an application for a process patent. Now what is the process, what does it consist of?

MR. BICKEL: All right, this would be very helpful to the Court. I think the claims perhaps would—

THE COURT: No, do not read me the claim. Tell me in non-technical layman's language, Mr. Bickel, what does the process consist of.

MR. BICKEL: All right. The process consists of passing the frozen blood cells through a channel or a tube, we might call it. They are passed through by the pressure of an inert gas at a high rate of speed, in one of the methods of using the invention. At the entrance to this channel the tube is heated to a high heat, and I believe that the disclosure says that this heat will be somewhere from 250 degrees centigrade to as high as 1100 degrees centigrade, depending upon the speed that you are using. Then, as the material passes through this channel, the temperature of the channel itself decreases, until at the end the material comes out at a temperature of from 37 to 50 degrees centigrade.

12 THE COURT: Let's see if I understand this correctly. The blood is a solid, it is a frozen solid, is it not?

MR. BICKEL: Yes.

THE COURT: And you push it through this tube?

MR. BICKEL: It is blown or it could be dropped. There could be a gravity drop system used.

THE COURT: Well, anyway, this frozen solid is passed through the tube?

MR. BICKEL: Yes, your Honor.

THE COURT: And the end of the tube is heated so as to thaw out the solid, is that it?

MR. BICKEL: Yes, the tube is very hot at the beginning and then it cools as the material passes through.

THE COURT: I see.

MR. BICKEL: And the material ends at the bottom of the tube. The material falls into an isotonic solution which is similar to the liquid of the blood stream and slightly saline solution, so that the end result would be comparable to liquid blood. And that is the process, your Honor, in, as you say, non-technical words. It is set forth in the claims, and I believe that the Court does have copies of the claims before it. The Patent Office has based its rejection upon a ruling—the only case which they cite, as a matter of fact, is one which this Court handed down some years ago, the Isenstead vs.
13 Watson, which your Honor may recall.

THE COURT: I do not recall it by name, but if you tell me what it was about, no doubt I shall recall it.

MR. BICKEL: This was a case wherein this Court held that the Patent Office should be particularly careful in medical patents, and the case dealt with a new medical formula and discussed the rules of utility to be applied to new medical formulas.

through our expert witness, is that indeed this process would produce a result which would not be harmful; that the harmful effects which the Patent Office mentioned—and they only mentioned one: they thought perhaps the blood cells would be scorched—that this will not occur. In other words, we have here, and we feel this is an essential distinction in the case, we have here not a new medicine. There is no new medicine here. There is no new chemical compound. This is a process claim. We are dealing with a known matter.

THE COURT: Then what does the process consist of?

MR. BICKEL: Thawing in a quick manner red blood cells.

THE COURT: But what is there patentable about it? What is the patentable feature?

MR. BICKEL: The patentable feature, your
11 Honor, is that no one before—and the Patent Office
has not questioned this in any manner—that no one before had invented or disclosed a device which would quickly thraw the frozen blood cells.

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THE COURT: I do not recall it by name, but if you tell me what it was about, no doubt I shall recall it.

MR. BICKEL: This was a case wherein this Court held that the Patent Office should be particularly careful in medical patents, and the case dealt with a new medical formula and discussed the rules of utility to be applied to new medical formulas.

THE COURT: What is the citation to the case, have you got it?

MR. BICKEL: Yes, your Honor. It is 157 F. Supp. 7. The plaintiffs feel that the Patent Office was erroneous in applying this case. We do not contend that the rule of this case is improper or anything of the sort. We simply contend that the Isenstead decision related to tests which should be required of new chemical compounds before they are administered into the human body; and it seems to make excellent logical sense, regardless of the law, because if a new form of matter is created, its properties are not necessarily predictable and certainly some testing should be required of a new form of matter before it is introduced into the human body.

Now, we simply contend that in this case we are not dealing with any new form of matter, we are dealing with human blood or animal blood, as we intend to
14 show that animal blood can be used successfully in
this process and very valuably; that there simply is no basis for applying the rule as to new chemical formulas to a process claim which involves no new form of matter and which is not contrary to any recognized scientific principle.

We intend to show the Court that this process follows recognized accepted standard laws of chemistry and physics, especially laws of physics; that no new form of matter is created; that the rules pertaining to so-called medical patents or new medicines to be used are not applicable to this case.

I believe, for purposes of the opening statement, unless the Court has further questions, this would terminate our opening statement.

OPENING STATEMENT BY COUNSEL ON BEHALF OF DEFENDANT

MR. ARMORE: May it please the Court, my name is Jack Armore. I represent the Patent Office, Patent Office counsel.

As plaintiffs' attorney has pointed out, the application for a patent in this case is concerned with a process for thawing or reconstituting frozen blood or red blood cells, the process consisting of passing the frozen blood through a heated chamber and receiving the frozen blood in an isotonic saline solution. The chamber is heated at the top, according to the disclosure in the claims, from 250 to 1100 degrees centigrade and it is heated at the bottom from 37 to 50 degrees centigrade, and there is a gradual drop in temperature from the top of the chamber to the bottom, and the blood is passed in a matter of seconds, one or two seconds.

Now, there are four claims under review by the Court at this time. They are Claims 17, 24, 25 and 26. These claims are process claims, generally directed to the process which I have just described. They vary with respect to temperature and with respect to the method of passing the blood through the heated chamber, either by way of gravity or by using an inert gas. Generally, these claims will stand or fall together. They involve the same type of subject matter.

Now, an important—

THE COURT: Just a moment. The claims in suit are 17, 24, 25 and 26, is that correct?

MR. ARMORE: That is correct, your Honor.

THE COURT: Very well.

MR. ARMORE: Now, as plaintiffs' counsel has indicated, an important consideration in this case is the question of utility. The claims have not been rejected on prior art, the claims have been rejected on the ground that they lack utility. They have been rejected on the ground that there has been no showing which would satis-

fy the statutory requirement of utility with respect to the product resulting from the claimed process:
16 that there is no evidence in the record showing that the product has any utility. Now—

THE COURT: The product is blood. Blood has utility, has it not?

MR. ARMORE: Well, your Honor, not necessarily. Primarily we are concerned—I think I can answer your question more effectively this way: primarily we are concerned with the specific utility disclosed in the application. The applicant is held to his disclosure of utility for the product resulting from the claimed process and we have to look to the application for the particular utility that he assigns to that product. And he is charged with that utility, and unless he has shown that utility, then he has not satisfied the statutory requirement for utility.

THE COURT: I do not think I made my question clear. The product of this process is blood. One does not have to demonstrate utility of blood, does one?

MR. ARMORE: Yes, your Honor, one does, because blood is an extremely labile substance. That means it tends to undergo changes. And when blood is taken out of the human body or is subjected to certain drastic conditions, such as high temperature, it may very well and very readily undergo changes which make it unsuitable for transfusion.

THE COURT: You mean, then, that it is not
17 shown that blood obtained by this process is in useful condition?

MR. ARMORE: That is correct, your Honor. And more specifically, it is not shown that this blood is useful for transfusion into a human being, and it is the position of the defendant in this case that the disclosure in the specification is specifically limited to utility encompassing transfusion into a human being. And I would like to refer your Honor now to portions of the specification that suggest or that indicate this particular utility. I would refer your Honor to page 1 of the specification. The sole disclosure as to utility in this case is found on page 1. I will read the pertinent portions. The first paragraph on that page states:

> "This invention relates to the reconstitution of frozen biological material and particularly to the reconstitution of frozen blood cells."

Reading from the second paragraph:

> "Previous methods for the reconstitution of frozen biological cellular material to render it suitable, for example, for human use, involved the heating of the cells in slow increments."

Now, this is the sole disclosure in the whole specification with respect to utility of the product resulting
18 from the claimed process. The sole disclosure is human use. Now, obviously, blood when it is intended for human use is intended for transfusion. Therefore, it is the position of the defendant, and this was the basis of the decision by the Patent Office Board of Appeals in denying the claims, that the plaintiffs have alleged as their sole utility that the product of the claimed process is a blood which is suitable for transfusion into a human being. This makes it a medical substance because blood obviously is used for medical purposes; and being a medical substance, under the requirements as laid down in the decision of Isenstead vs. Watson—which plaintiffs' counsel has alluded to and which I will go into further; I am sure your Honor will be well aware of that case when you have seen it—that decision clearly indicates that an application for a patent involving a medical substance, whether the claims are directed to a compound or whether the claims are directed to a process which results in the medical compound, in such application the utility must be established by significant clinical testing, as your Honor indicated in that decision, by at least two physicians, by more than one physician.

Now, I would like to refer your Honor also to the
last page—well, I would like to read further on page 1,
I think it will be very useful in the light of further argu-
ments as they will be developed, and part of page
19 2. Continuing on page 1, in the middle of the
paragraph, the bottom paragraph:

> "Thus, red blood cells are slowly heated"—

the application is discussing the prior process, prior to this process—

> "Thus, red blood cells are slowly heated, usually being held for a period of time at one temperature condition, then raised to a slightly higher temperature condition, and so on, until the desired temperature of 37 degrees centigrade is attained."

I refer the Court now to page—

THE COURT: May I ask you, as a matter of information, what is the Fahrenheit equivalent of 37 degrees centigrade? Do you know? Is that the normal temperature of blood?

MR. ARMORE: The Fahrenheit is a little less than twice the centigrade, so that this would roughly be about near 60 degrees Fahrenheit. I think it would be in the area of about 65 or 60 degrees Fahrenheit.

THE COURT: In other words, cooler than the normal body?

MR. ARMORE: Well, your Honor—yes, I would say so, yes, that is correct. A centigrade is five-ninths of a Fahrenheit degree.

Now, your Honor, I think it would be useful, and this
would answer a question that you had previously
20 asked, to refer to page 2 of the specification, where
the specification points out the results of prior art
processes and what can happen to the blood:

> "The processes referred to above are not only slow but tend to produce denaturation"—

THE COURT: Where are you reading from?

MR. ARMORE: I am reading from the top of page 2 of the specification.

THE COURT: Do you mean page 3? The first page is marked—

MR. ARMORE: I had read from the first page. Now I am turning to page 2 of the specification.

THE COURT: I see. I turned over two pages. They stuck together. Proceed. I have it now.

MR. ARMORE: "The processes referred to"—meaning the prior art processes, the slow heating processes—"referred to above are not only slow but tend to produce denaturation"—that would mean changes in the blood composition—"within the cell as the temperature rises, this condition being occasioned as deleterious reactions occur within the corpuscle"—that is, the red blood corpuscle—"due to the increased activity thereof as the temperature rises."

21 So, your Honor sees that under certain conditions the blood will change its nature, it will be denatured; and when it becomes denatured it is no longer suitable for human transfusion.

Now, I would refer your Honor to the last paragraph—

THE COURT: Just what is meant by denatured in that connection?

MR. ARMORE: I can best explain it this way: denatured blood is blood which has been chemically and physically changed with respect to its components. The red blood corpuscles may break down, the hemoglobin may break down, the blood no longer has the same characteristics. Denatured blood cannot be transfused into a human being, or should not be.

Now, the last paragraph on that page:

> "It is a further object of this invention to describe a method for the reconstitution of frozen red blood cells, which method conditions the cells for immediate use."

Now, I am reading this paragraph and stressing it because decisions—I have read this paragraph to indicate that the product is capable of immediate use, because arguments presented by the plaintiff in his trial brief refer to decisions involving intermediates, where a substance is claimed which has a function as an inter-
22 mediate can be used to prepare other substances;
but here we are not dealing with an intermediate, we are dealing with a substance which is intended for immediate use. And that is a point that I think might well be kept in mind.

Now, there are two important issues in the case. One issue is, does the disclosure in the specification involve and is it limited to a medical substance intended for human use. I suggest and I submit, in view of the previous discussion, that the disclosure in the application is strictly limited to a medical—to a process which will result in a medical substance intended for human use.

Another issue with which the Court is confronted is, are the claims in such an application patentable in the absence of any showing of clinical testing. And the answer to that, in view of the decision in Isenstead vs. Watson, which I will discuss in more detail in my final argument, I submit is no, the rule being pretty well laid down in that decision.

THE COURT: Now what is the second issue?

MR. ARMORE: The second issue is whether claims in an application directed to a process resulting in a medical product, should such claims be patentable in the absence of a showing that the product is suitable for human use.

Now, if your Honor please, I would like to discuss as briefly as I can certain points that have been
23 brought out in the plaintiffs' trial brief, if I may
do so, and which I think are rather material to this case. On page 2, in the middle of the page, the brief notes:

> "It should be noted that it is nowhere claimed in the disclosure or the claims that the thawed blood cells are to be used for human transfusion."

In the light of what I have just said, we deny that that statement is accurate. We suggest that the evidence clearly indicates a reading of the specification makes it quite clear that the disclosure of the claimed process is directed for human use, that in effect the product of the claimed process is a medical substance intended for human use.

On page 3 the plaintiff postulates three issues, and I submit that each one of these three issues is based on a wrong premise. I will not read each one of these three issues, to save the time of the Court, but I will briefly indicate that in issue one, where the issue states that the described process contravenes no scientific principle, that is a false premise because heating blood to the high temperatures required by the claimed process does contravene what has been generally considered to be true heretofore, namely, that heating blood to a high temperature tends to decompose certain constituents of the blood, particularly the proteins, such as the homo-
24 globin; and, therefore, in effect the claimed process does tend to contravene certain known scientific principles.

Now, that is not to say that the Patent Office alleges specifically that the process will not work. That is to say that the plaintiff, since he is claiming a process which results in a medical compound, has not met the standard or the requirement laid down by the law as set forth in Isenstead vs. Watson, in showing that the product is useful.

THE COURT: I think I get your point. May I inquire, was an appeal taken in the Isenstead case?

MR. ARMORE: I would say no, your Honor, because I shepherdized the Isenstead case before I came into court and I did not notice an appeal having been taken. But it has been followed by the Board of Appeals of the Patent Office and it also has been cited and followed in a decision by a United States District Court in Illinois, of which plaintiffs' counsel is a member of the Bar.

THE COURT: Do you have the citation to that?

MR. ARMORE: Yes, your Honor, I have. The citation is Armour and Co. vs. Wilson and Co., United States District Court, Northern District of Illinois, Eastern Division, 168 F. Supp. 353, 119 U.S.P.Q. 365.

And the third issue refers to the fact, on page 3, refers
to the fact that the process produces no new chemi-
25 cal compound. Briefly stated, the plaintiff appears
to claim or appears to argue that, for one thing,
he starts with blood—

THE COURT: Really, each of the three issues is just a different way of stating the same question, is it not?

MR. ARMORE: Well, not precisely, your Honor, not quite precisely.

THE COURT: No, but substantially.

MR. ARMORE: May I point out one difference in the third issue?

THE COURT: It is just a question of phraseology, really.

MR. ARMORE: May I point out one difference in the third issue that I think is rather important?

THE COURT: Yes, of course.

MR. ARMORE: In the third issue it appears to me that the plaintiff is attempting to allege that Isenstead vs. Watson has been applied specifically to a compound and he is claiming a method. And I consider that the decision in Isenstead vs. Watson is applicable to an application involving a medical material.

THE COURT: But how does the so-called third issue differ from the first two? I do not see it, really, except it is the same thing said in different ways.

MR. ARMORE: Well, it is pretty close to those
26 two, your Honor, so I won't discuss those two
issues any further.

Your Honor, on the bottom of page 3 and on the pages following, plaintiff has set forth a number of points with respect to the requirement for a showing of statutory utility.

THE COURT: I think these are fairly elementary points, they are hornbook law, pretty much; isn't that so?

MR. ARMORE: That is correct, your Honor, and I don't think I am going to spend much time on them at all, except to point this out, that a reference is made to two decisions, one the Nelson decision and the other the Krimmel decision, both decisions by the Court of Customs and Patent Appeals, cases which have recently been decided by the Court of Customs and Patent Appeals, and he relies on these cases. Now, with your Honor's permission, I will postpone a detailed consideration of those cases and show why they do not apply to the present situation for my final argument.

THE COURT: Which case are you referring to?

MR. ARMORE: For example, point two, at the top of page 4, which at the bottom of the statement is followed by application of Nelson; page 4 of the plaintiffs' brief, point two at the top of that page.

THE COURT: Yes, I see it. And what is the other case?

27 MR. ARMORE: The other case is the Krimmel case. The Krimmel case appears for the first time at the top of page 6.

THE COURT: Has it been reported in the Federal Second advance sheets?

MR. ARMORE: I don't think it has, your Honor. These are very recent decisions.

THE COURT: I have the Federal Second, but I do not have the U. S. Patent Quarterly in my chambers.

MR. ARMORE: I am sorry, I know that you prefer Federal citations, but I don't think they have been reported.

THE COURT: Very well. You suggest that you defer argument on those two cases until later. That is entirely satisfactory to the Court.

MR. ARMORE: That is correct, your Honor, unless the Court prefers I do it now. I can do it in either event.

I may point out—I will then go on to just briefly mention in a very general fashion the other decisions which are set forth in the plaintiff's brief. Most of the decisions here relate to non-medical—involve cases with non-medical materials and, therefore, I submit that they are not at all pertinent. One case found in the middle of page 5, Blicke vs. Treves, under point seven, that case did involve a compound which was characterized in the disclosure
28 as having medical properties, but the disclosure did not limit the application of the compound to human beings and the showing was made in that case that it was effective on animals and the Court held that it was sufficient showing of utility.

Of course, in this case our position is that the disclosure is limited to human beings and, moreover, there is no showing whatsoever that the product is effective with respect to anything.

Now, I would like to refer your Honor to page 8 of the plaintiffs' brief, the middle paragraph on that page. Before I refer to this paragraph specifically, I think it would be useful to point out that the claims in this case have been consistently refused by the Office on the ground that there has been no showing that the claimed process will result in a product which will have the properties which have been indicated in the specification. The plaintiff never actually met that objection or rejection head on.

THE COURT: I do not think you need labor this middle paragraph. It seems to me that before a person gets patent protection he has got to demonstrate that he is entitled to a patent.

MR. ARMORE: That is correct, your Honor.

THE COURT: Yes, I do not think you need labor that middle paragraph.

29 MR. ARMORE: All right, I won't mention it, except I would like to mention one point in connection with that. In that paragraph the plaintiff in effect admits that he does not have a completed invention, the product has never been tried on human beings and that further work is necessary.

THE COURT: Very well.

MR. ARMORE: Now, the last point that I am going to consider in connection with my opening argument and in connection with the brief is found both on pages 7 and 8 of the trial brief and was also referred to by plaintiffs' counsel in his opening statement. In both of these pages the plaintiff refers to the fact that his product is useful for laboratory testing and he indicates that he intends to produce evidence to show that the thawed blood which results from the claimed process will be useful for laboratory testing. Now, I would like to suggest to the Court that there has been no disclosure whatsoever in the specification that the product of the claimed process is intended to be used for laboratory testing. Furthermore, I would like to suggest, too, that it would be improper for any evidence to be produced—incidentally, no arguments have ever been advanced during the prosecution in the Patent Office that the product is useful for laboratory test purposes. I suggest that any evidence introduced along those lines would be improper, even though this is a suit
30 under 35 U. S. C. 145. As your Honor as well
aware, from decisions in this Court and by the Court of Appeals, while a suit under 35 U. S. C. 145 is a suit de novo, nevertheless the Court will not ignore what has gone before—

THE COURT: I do not follow you. What was your point?

MR. ARMORE: As your Honor knows, while a suit under 35 U. S. C. 145 is considered a suit de novo, nevertheless decisions by this Court, as in Shering vs. Marzall and other cases, have held that the Court cannot ignore what has gone before.

THE COURT: Of course not.

MR. ARMORE: Furthermore, even though this is a suit de novo, the plaintiff is not free to bring in evidence along lines purporting to support arguments which have not been presented hitherto to the Patent Office. Furthermore, he is not permitted to introduce new evidence which may amount to nothing more than either suppression, bad faith or gross negligence.

THE COURT: May amount to what?

MR. ARMORE: Suppression, bad faith or gross negligence. Where he, as he indicates here, will attempt to introduce evidence indicating that the product is suitable for laboratory purposes, no such argument, no such evidence having been submitted to the Patent Office
31 during the whole course of prosecution, the plaintiff cannot introduce that type of evidence even in a suit under 35 U. S. C. 145.

THE COURT: Why not?

MR. ARMORE: Because, as pointed out in the decisions in Shering Corp. vs. Marzall, 101 F. Supp. 571, page 573; a more recent decision in Killian vs. Watson, this does not appear in the Federal Supplement, the only citation I have is 121 U.S.P.Q. 507, —

THE COURT: What Court is that?

MR. ARMORE: In the United States District Court for the District of Columbia. It is in this Court.

THE COURT: What Judge?

MR. ARMORE: Judge Murphy.

THE COURT: The first case that you rely on is 101 F. Supp. 571, is that it?

MR. ARMORE: That is correct, your Honor. There are a number of other cases.

THE COURT: Always give me your best one first.

MR. ARMORE: All right, your Honor, that is the best one.

THE COURT: At least, the one you consider best. In a non-jury case I believe in being rather liberal in allowing parties to make their record.

MR. ARMORE: Your Honor, may I just point 32 this out, that these decisions that I have cited and other decisions which I have not yet cited, which all go to the same point, it has been uniformly held that even in a suit of this type the plaintiff may not introduce new evidence which does not strengthen contentions already made before the Patent Office.

THE COURT: Very well. This is not the time to argue the matter. Let's wait until evidence is tendered. and if you object, I will hear the objection.

MR. ARMORE: All right, your Honor. Thank you.

THE COURT: You may proceed.

MR. BICKEL: We are now ready to call our first witness, your Honor, Dr. Lyell Klotz.

Thereupon,

LYELL J. KLOTZ

called on behalf of the plaintiffs, and having been duly sworn, was examined and testified as follows:

DIRECT EXAMINATION

BY MR. BICKEL:

Q Will you state your full name, please? A Lyell J. Klotz.

THE COURT: What is your name, sir?

THE WITNESS: Lyell J. Klotz.

THE COURT: You dropped your voice when you got to your last name, so I did not get it.

33 THE WITNESS: Klotz, K-l-o-t-z, L-y-e-l-l.

THE COURT: Thank you.

BY MR. BICKELL:

Q What is your occupation, Dr. Klotz? A I am Director of Research for the Central Pharmaceutical Company of Seymour, Indiana. In conjunction with my work—

THE COURT: Mr. Witness, you will have to talk so everybody can hear you. You may use the microphone if you wish. You are in a big courtroom, you know, you are not in your office or in your laboratory.

THE WITNESS: I am Director of Research for the Central Pharmaceutical Company of Seymour, Indiana, in conjunction with my position as Director of Pharmaceutical Research for the Commonwealth Engineering Company of Dayton, Ohio.

Is that adequate, your Honor?

THE COURT: You may not address questions to the Court.

THE WITNESS: Sorry, sir.

MY MR. BICKEL:

Q Where do you reside, then, Dr. Klotz? A I reside at 3102 Marigold Court, Kettering, Ohio.

Q Would you describe to the Court your technical education? A I received a Bachelor of Science
34 degree from the University of Nebraska in 1928,
the Master of Science degree from the University of Nebraska in 1929, both in pharmacy. I received the Doctor of Philosophy degree in 1934 from the University of Florida, with a major in pharmaceutical chemistry.

Q Now would you describe to the Court your occupational experience in the pharmaceutical and medical field? A I have served as a faculty member at the Medical College of South Carolina and at the University of South Carolina, where I taught subjects in pharmacy and related fields. I also served as a faculty member at the Ferris Institute in Big Rapids, Michigan, in the subjects of pharmacy and biology. I served as head of the Chemistry Department and Director of the Department of Student Health at Southwestern State College in Weatherford, Oklahoma. Subsequently, as Dean of the Cincinnati College of Pharmacy, Cincinnati, Ohio, for a period of seven years. Subsequent to that, I served as Director of Research for Lloyd Brothers, Inc., a pharmaceutical manufacturer, Cincinnati, Ohio, until May of this past year.

THE COURT: I think the witness is well qualified. Are you trying to qualify him as a chemist in the pharmaceutical field?

MR. BICKEL: In the pharmaceutical field, your Honor, yes.

35 THE COURT: I think he is qualified. I do not think Government counsel will question that.

MR. ARMORE: I do not, your Honor.

BY MR. BICKEL:

Q Dr. Klotz, have you read the file wrapper of the patent application in suit here so that you are generally familiar with the subject matter involved? A Yes, sir, I have reviewed it.

THE COURT: May I interrupt you, Mr. Bickel? Are you going to offer the file wrapper in evidence?

MR. BICKEL: Yes, your Honor.

THE COURT: I would suggest this might be an appropriate time to do it, in view of the fact that you are referring to it.

MR. BICKEL: May we have this marked as Plaintiffs' Exhibit for identification? Your Honor, I have here a certified copy of the file wrapper of Patent Application No. 370533, the application in suit, and I now offer it into evidence.

THE COURT: Are you offering it in evidence?

MR. BICKEL: Yes, your Honor.

(File Wrapper marked Plaintiffs' Exhibit No. 1 and received in evidence.)

THE COURT: You may proceed.

36 BY MR. BICKEL:

Q Dr. Klotz, do you know what the percentage of water is in the composition of a red blood cell? A I believe about eighty per cent.

Q Are you familiar with the physical constituent which is known as the heat of fusion? A Yes, sir.

Q Would you explain to the Court what this principle is, with special reference to water? A The heat of fusion is defined as the number of calories of heat required to convert a substance in the solid state into that same substance in the liquid state. With reference to water the figure, I believe, is approximately eighty calories of heat per gram, which is the amount of heat required to melt one gram of water as ice into the aqueous liquid state.

Q And applying that principle to water, how many calories of heat are necessary to raise one gram of water once it has been melted one degree centigrade? A One calory, sir.

Q But it requires eighty calories simply to change it from water into—excuse me—from ice into water without changing temperature? A That is true.

37 Q Is this principle of heat of fusion a fairly established and constant principle and can you think of any examples to show that? A Oh, yes, this is one of the fundamental physical properties of matter. I believe, if I remember correctly, this was first expounded back in the 1700s. Heat of fusion is a very well established principle which is invariable within very narrow limits at all temperatures for all substances.

Q I see. Then if the time of explosure of a material to a heat—and, for example, heat of a thousand degrees, or any heat which you might choose—if the time of exposure is sufficiently small and the material is in its solid state, is it possible for that material to be exposed to the heat and yet not change its temperature? A I would certainly say yes, under the proper conditions.

THE COURT: I am afraid I did not follow the question.

MR. BICKEL: I apologize to the Court, your Honor.

THE COURT: No, that is all right. Would you mind repeating it?

MR. BICKEL: Not at all, your Honor.

THE COURT: It involves a technical concept and I did not grasp it the first time.

38 MR. BICKEL: Perhaps I could make it even clearer. If we assume—

THE COURT: Suppose you read the question.

(The last question was read by the Reporter.)

THE COURT: What was the answer?

(The last question was read by the Reporter.)

THE COURT: Is that the same principle as the principle of latent heat?

THE WITNESS: Latent heat of fusion, your Honor.

THE COURT: Heat of fusion and latent heat are synonymous, are they?

THE WITNESS: Latent heat of fusion is synonymous with heat of fusion.

THE COURT: Yes. When I studied physics they used to call it latent heat rather than heat of fusion. It is the change in nomenclature that puzzled me.

THE WITNESS: I think it's the same, sir.

BY MR. BICKEL:

Q Then with reference to the file wrapper of the patent in suit—

MR. BICKEL: If I may, your Honor, I will read briefly from page 8 and ask a question of the witness.

Q Page 8 of the file wrapper, this statement is made:

39 "The lability and the size of the particles which is normally small will vary slightly from sample to sample but these factors are ordinarily of less importance than the original temperature condition of the particles and accordingly the latter governs the choice of tube length, temperature gradient and specific temperatures employed as well as the velocity to be imparted to the particles in their density."

Now, with reference to that, if the proper adjustments of time of exposure to the heat are made, is it possible to pass frozen blood cells at zero degrees centigrade even through 1100 degrees centigrade temperature without changing their temperature from zero degrees centigrade? A Well, I would think so, sir. It seems to me it's analogous to passing your hand through an open flame. As I recall it, the temperature of a Bunson flame is about fifteen to sixteen hundred degrees centigrade. I have personnely passed my hand through a gas flame a good many times without burning my hand in any way, provided I did it rapidly enough.

Q Correct. And is the cell structure of your hand roughly analogous to that of human blood or red blood cells? A I would say, in the sense that all biological material is made up of individual cells, that there certainly—

THE COURT: I wonder why we need all this. 40 This is very interesting and instructive, but why do we need this line of inquiry for the purpose of this case?

MR. BICKEL: Your Honor—

THE COURT: Well, I am not going to ask counsel to discuss this matter, but I am going to ask counsel to get as promptly as possible to the point that I have to decide.

MR. BICKEL: Your Honor, this is the point that this invention follows recognized scientific principles. I have another question or two—

THE COURT: I do not understand that the Patent Office questions the fact that you can thaw out frozen blood by your process. What they question is whether the blood that you get by your process is a useful product in the technical sense.

Isn't that the point?

MR. ARMORE: We question whether it's suitable—

THE COURT: Do I correctly understand your point?

MR. ARMORE: Except for one point.

THE COURT: Beg pardon?

MR. ARMORE: Except for one point, your Honor. We question whether it is suitable for human transfusion.

THE COURT: I understand. Then the answer to my question is yes.

MR. ARMORE: Yes, your Honor.

41 THE COURT: Very well.

MR. BICKEL: Your Honor, the Patent Office has stated, and, as a matter of fact, it was stated in the argument here that the high heat to which the blood cells are heated would cause them to deteriorate; and the point of this testimony was to bring out this high heat does not necessarily mean that the blood cells reach a high heat.

THE COURT: Very well. I do not want to curtail your presentation unduly, I want you to have every opportunity to present your case, but I suggest that we get to the issues as promptly as we can

MR. BICKEL: Yes, your Honor.

BY MR. BICKEL:

Q Are you familiar, Dr. Klotz, with any uses for red blood cells other than for purposes of human transfusion?

A Yes, sir.

Q Would you describe to the Court any uses of red blood cells—

MR. ARMORE: Your Honor, I object to that line of questioning in view of the fact that the disclosure in the specification is limited exclusively to human transfusion.

and for the reasons that I have indicated before, in view of the decisions I have referred to before in my opening remarks.

THE COURT: Objection overruled. You may answer.

42 THE WITNESS: Yes, sir, I do. Red blood cells are used in several diagnostic procedures used by laboratories as an aid in the diagnosis of human disease.

BY MR. BICKEL:

Q Are there any uses which would be helpful in having frozen blood cells at hand in a laboratory, with reference to animal blood? A Yes, I would say so.

Q Would you explain some such test?

MR. ARMORE: Your Honor, I will not continue my objections along this line, but you will understand that—

THE COURT: I am going to allow this testimony. What weight I shall attach to it is a different matter, but I will allow it to be given.

MR. ARMORE: All right, your Honor, and I will make no further objections along this line and it will be understood that—

THE COURT: No, it is understood that your objection stands to this entire line of inquiry.

MR. ARMORE: That is correct, your Honor.

THE WITNESS: May I have the question again, sir?

(The last question was read by the Reporter.)

THE WITNESS: Yes—I am confused as to the question. May I hear the question before that, please?

43 THE COURT: Suppose you repeat your question, Mr. Bickel.

MR. BICKEL: May I rephrase it, your Honor?

BY MR. BICKEL:

Q I am now referring to tests wherein animal blood might be used. Would you describe any laboratory tests wherein animal blood might be used as a standard test sample? A Yes. The original Wasserman test for the presence of syphillis, and I believe all subsequent modifications of that test, require the use of sheep blood corpuscles as an integral part of the technique, and to the best of my knowledge the test cannot be carried out without sheep blood corpuscles or those of a related animal.

Q In your opinion, as one who has worked in laboratories, would it be helpful to have in a hospital laboratory a supply of sheep blood corpuscles stored in a frozen form? A I would say yes, for the reason that ordinary storage of sheep blood corpuscles results in their deterioration within periods of possibly two weeks or less. Therefore, it is necessary to constantly reconstitute the supply of corpuscles in order to carry out this particular examination.

THE COURT: I think we will take our usual mid-afternoon recess.

(Brief recess.)

44 THE COURT: You may proceed.

BY MR. BICKELL:

Q Dr. Klotz, having read the file wrapper of this application, did you observe anything in the proposed process, as to application of heat and adjustments of the variables of time and length of exposure, which would be contrary to recognized scientific principles? A I don't think so, sir.

Q In your opinion, if the length of time of exposure to high temperature is sufficiently small, is it possible to pass red blood cells through a high temperature without scorching them? A I see no reason why not. I would certainly think so.

MR. BICKEL: No further questions.

CROSS-EXAMINATION

BY MR. ARMORE:

Q Dr. Klotz, you have testified that you can't foresee any changes in passing frozen blood quickly through a high temperature, and you gave as an illustration of fact that you can pass your hand through a Bunson burner and you won't even feel it, is that correct? A I think so.

Q Suppose your hand were wet, would you feel it?
A I don't understand the question.

45 Q If your hand were—

THE COURT: Suppose you read the question.

(The last full question was read by the Reporter.)

THE COURT: Feel what?

MR. ARMORE: Feel the effect of the heat of the flame.

THE WITNESS: If the heat were inadequate, no; if the heat were adequate, I think yes.

THE COURT: What is your answer?

THE WITNESS: If the heat were adequate, perhaps yes; if the heat were inadequate, perhaps no.

BY MR. ARMORE:

Q We are talking about a Bunson burner, Doctor. A Sir, I would feel the heat of boiling water if my hand remained long enough in that flame.

Q Then you would feel the effect of the heat if you passed your wet hand through a Bunson burner, is that correct? A No, sir, I did not make that statement.

Q Would you feel any effect whatsoever if you passed your wet hand through a Bunson burner? A I think again it would depend entirely on the rate at which my hand went through the Bunson burner.

Q Is it true that when blood is removed from the body it tends to undergo changes?

46 A Yes, sir.

Q When blood has been subjected to various factors, such as either acid or alkali or heat, will changes be produced in the blood? A Yes, sir.

Q When blood has been changed as a result of such factors is the blood generally considered denatured blood? A Yes, sir.

Q What would be the result of transfusing denatured blood into a human being? A It would—

MR. BICKEL: Your Honor, I object to this question.

THE COURT: Read the question.

(The last question was read by the Reporter.)

THE COURT: Objection overruled.

THE WITNESS: May I hear the question again?

THE COURT: Read the question again, please.

(The last question was reread by the Reporter.)

THE WITNESS: It would depend, sir, I think, completely upon the degree of denaturation. Would you care me to amplify my answer?

MR. ARMORE: Yes, you may amplify.

THE WITNESS: If the degree of denaturation were
sufficiently severe so that the proteins making up
47 the cellular substance were denatured, toxic re-
actions might be produced, but—

THE COURT: By toxic you mean the human being might be poisoned?

THE WITNESS: Yes, sir. But, sir, on the other hand, blood is transfused often after storage up to thirty days and during that thirty days of ordinary storage in the refrigerator some degree of denaturation is constantly occurring. Therefore, it is impossible to answer the question yes or no; it depends entirely upon the degree of denaturation, I think, as to the potential dangers and hazards involved.

BY MR. ARMORE:

Q Therefore, it is true that you have testified that heat will tend to denature blood? A Yes, sir.

Q And that the degree of denaturation—any adverse effects upon transfusing that blood will depend upon the degree of denaturation? A Yes, sir.

Q Which, in turn, will depend upon the amount of heat that has been applied to the blood? A Yes, sir.

MR. ARMORE: That is all, your Honor.

THE COURT: Anything further?

48 MR. BICKEL: Yes, two questions to clarify something, your Honor.

REDIRECT EXAMINATION

BY MR. BICKEL:

Q When you stated that heat would tend to denature blood, Dr. Klotz, did you mean that the heat to which the blood itself had risen or the degree of external heat which was applied? A I meant the heat to which the blood—will you ask the question again, please?

THE COURT: Will you read the question?

(The last question was read by the Reporter.)

A I intended to mean the heat to which the blood had risen; but I must also qualify that answer in terms of the amount of time to which that blood was exposed to that heat.

Q Dr. Klotz, taking into account the phenomenon of heat of fusion or latent heat, to which you earlier testified, if, let us say, blood at zero degrees centigrade in its frozen state were exposed to a high temperature for such a sufficiently small length of time that it had merely liquified and had not begun to rise in temperature, would it make any difference at all how much—what the degree of outside heat which had been applied was? A It certainly would not seem so.

49 Q Is it possible, applying the principle of heat of fusion again, together with the variables of time of exposure, which we have discussed, to pass blood through, frozen blood, through a temperature gradient of let's say 1100 degrees to 37 degrees, provided your speed adjustment is correct, and have the blood come out the discharge end having never risen above 37 degrees centigrade itself? A It would certainly seem so, based on physical principles.

MR. BICKEL: No other questions.

THE COURT: Anything else?

MR. ARMORE: No other questions, your Honor.

THE COURT: You may step down.

(Witness excused.)

MR. BICKEL: Your Honor, the plaintiff rests.

MR. ARMORE: Your Honor, you will accept final arguments?

THE COURT: Yes. Before we do that, are you going to offer any evidence?

MR. ARMORE: Yes, I will offer into evidence the defendant's exhibits which have been informally handed to the Court, Exhibits A to E. I will now offer Defendant's Exhibits A to E in evidence.

THE COURT: They may be admitted.

50 (Defendant's Exhibits A—Tullis-Blood Cells & Plasma Proteins, 1953, Academic Press, NYC, pp 207-208; B—Print of Drawing; C—Examiner's Answer; D—Decision of Board of Appeals; E—Decision on Reconsideration; were marked Defendant's Exhibit No. 1 and received in evidence.)

THE COURT: Do you rest?

MR. ARMORE: Yes, your Honor.

THE COURT: Now what was your request about final argument?

MR. ARMORE: I asked you whether you will accept final argument.

THE COURT: Yes, I will be very glad to hear final argument. Are you ready to proceed?

MR. BICKEL: I am, your Honor. Your Honor, having not appeared in this Court before, does the Court have any limitation upon length of time?

THE COURT: No.

MR. BICKEL: I don't plan a lengthy argument.

THE COURT: You may proceed as long as you wish so long as you are making contributions.

MR. BICKEL: Thank you, your Honor.

CLOSING ARGUMENT BY COUNSEL ON BEHALF OF PLAINTIFFS

MR. BICKEL: I believe, as an important preliminary
to my discussion, I should point out that the state-
51 ment that the government counsel has made here
as to the utility which we have claimed in the application does not seem to be correct. He implied that we had limited our claim of utility to human use because of certain statements made upon page 1 of the specifications—I believe the Court has a copy—and he read therefrom the final paragraph on page 1, the first sentence thereof, where it says previous methods for reconstitution of material.

I point out to the Court this is not the claim of utility of the patent, this is a discussion of previous methods of reconstitution of material. That discussion in that paragraph has nothing whatsoever to do with the claims of the application in suit.

THE COURT: I have not as yet read your specification. I am going to overnight, but do you in your specification point out what uses you are going to put this process to?

MR. BICKEL: No, your Honor; this is a process, and we point out that it is a process for quick reconstitution or thawing of the blood cells, and we believe that the quick reconstitution itself is a usefulness, is a utility.

THE COURT: But do you point out what the utility is? That is my question.

MR. BICKEL: We do not discuss it at length, your
Honor; and, furthermore, we do not believe that it
52 is necessary to point out every possible use of a
proposed invention.

THE COURT: Of course it is not necessary, but I am only asking you the question whether you did or not.

MR. BICKEL: No, your Honor, it is not pointed out.

THE COURT: Did you point out any use?

MR. BICKEL: The use of it as a process for quick thawing, and that is the only use.

THE COURT: Perhaps I do not make my question clear. Does your specification point out any particular purpose for which the blood processed by this method may be used?

MR. BICKEL: I didn't understand your question at first, your Honor.

No, there is no mention at all of the use to be made of the resulting product.

THE COURT: I do not think the law requires that the applicant point out the uses, but it is helpful if he does.

MR. BICKEL: Yes, your Honor. And one other point
which we might mention before beginning our argument.
All the way through in this case—and I believe really
this is the essence of the case—the Patent Office has relied
upon the fact that blood when heated does tend to, we
might say, disintegrate; in other words, it loses its valuable
position for use in transfusion purposes. But counsel
for the defendant and the Patent Office in the
53 hearings before it continually confused the applying
of external heat with the fact that the blood
itself must rise in temperature above body temperature
before harmful effects occurred. They assumed that because
you apply 1100 degrees centigrade temperature to
the blood, that it, itself, would rise to a high temperature.
And we feel that this is the basic erroneous assumption

which they have made all the way through the case, and that in fact the testimony of Dr. Klotz shows that if the speed is adjusted—which is a mechanical adjustment—as pointed out in the disclosure of the application, that the blood may be passed through this tube without its own temperature having exceeded 37 degrees centigrade, no matter what external temperature is applied, applying the principle of heat of fusion, wherein heat is absorbed in the frozen state without any change of temperature of the material which is so absorbing the heat.

And with that preliminary statement, I would call the Court's attention to certain authorities which we feel are exceedingly important in this case. I discussed in my opening statement the Isenstead case, which the Court has referred to. Since the Isenstead case was decided there have been two cases to which we call the Court's attention in the Court of Customs and Patent Appeals, which dealt with similar subject matter. These are cited to the Court not as binding authority on this Court, of course, but they are submitted—

54 THE COURT: I would regard a decision of the Court of Customs and Patent Appeals, even though not technically binding, as very persuasive and very important.

MR. BICKEL: We feel they would be extremely informative to the Court.

THE COURT: Yes. I have a very high regard for that Court.

MR. BICKEL: Now, the decision of In Re Krimmel, which defense counsel discussed, we have been unable to find in the advance sheets. It is perhaps printed by now, your Honor, but I do have a copy of that decision as appeared in U.S. Patent Quarterly, if the Court would like to have it.

THE COURT: I would like to have it.

(The document was handed to the Court.)

THE COURT: That is very helpful, I am sure. Thank you very much.

MR. BICKEL: Yes, your Honor. I am sorry that I wasn't able to get the advance sheet citation because it is possible within the last week or two it has come out, but at the time of writing the brief it had not yet come out.

The Krimmel case involved a patent application wherein the applicant had specified that the material was for pharmaceutical uses. The applicant had not specified that the material was to be used for human use. And
55 I call the Court's attention particularly to the statements made at page 220 of the U.S.P.Q. citation, wherein the Court of Customs and Patent Appeals discussed this fact. And I don't want to bore the Court with reading, but may I read a pertinent portion?

> "Although we have no doubt that the Patent Office has, in the case at bar, acted in good faith and with proper motives, the fact remains that the Patent Office has not been charged by Congress with the task of protecting the public against possible misuse of chemical patents. There is nothing in the patent statute or any other statutes called to our attention which gives the Patent Office the right or the duty to require an applicant to prove that compounds or other materials which he is claiming, and which he has stated are use for pharmaceutical applications, are safe, effective, and reliable for use with humans."

THE COURT: You know, without detracting one bit from what I said about having a high regard for the Court of Customs and Patent Appeals, with due deference I do not agree with that statement.

MR. BICKEL: Your Honor, the statement we
56 are offering to the Court as informative of the views of that Court, but our position is this, that this case does not involve a new chemical formula, it involves a process.

THE COURT: I know it involves a process, but if by means of that process you might put on the market a deleterious product I think that is a matter of concern. As I said in the Isenstead case, we have to look at those matters realistically. The Patent Office, of course, does not guarantee usefulness, but the public looks upon it as an imprimatur; they say they would not have given a patent if this was a harmful substance.

MR. BICKEL: Right, Your Honor, I believe that our position is not inconsistent with the Isenstead case.

THE COURT: I know. You would limit the Isenstead case to a product.

MR. BICKEL: No, your Honor, that is a limitation that the Government counsel here has—

THE COURT: Then how would you limit it?

MR. BICKEL: Well, it is limited to a situation wherein it cannot be accurately predicted scientifically what the effects will be of the resulting product.

THE COURT: I should have thought that you would make a series of tests and then submit affidavits to the Patent Office embodying the results of those tests.

MR. BICKEL: Your Honor, there is a very good
57 reason in this case, which I think this is a good
time to point out to the Court. To perfect this
device to the point of using it on human beings would
require a considerable and large expenditure of money.

THE COURT: I assume that, but have you made experiments on animals?

MR. BICKEL: Your Honor, no opportunity was given us by the Patent Office to do so.

THE COURT: It seems to me that that should have been done before you filed your application and submitted affidavits showing what you have done. In other words, patents are not granted to protect experimentation, they are granted only when the experimentation successfully culminates in a result.

MR. BICKEL: Correct, your Honor. The question before the Court, then, is how does an applicant go about showing that that result will be accomplished. Is it necessary to produce tests, or where you can show that it is perfectly sound from a physical sense is it not correct. We believe that the courts have repeatedly ruled upon this question and that the law is fairly well settled on the point. I would like to discuss that with you.

THE COURT: Apparently the Patent Office is not satisfied unless there are actual tests, and I do not know that I would criticize the Patent Office for exacting
58 tests. We are dealing, as I say, with human beings.

Now, assuming that this may be used for animal blood, but you do not say in your specification that this should be used only for animal blood and we have not reached a stage where we can suggest that it be used on human beings.

If you had said that in your specification, the situation would be entirely different.

MR. BICKEL: We do not believe, your Honor, that the law requires such a statement and that is with all deference to the Court. I would like to discuss the authorities.

THE COURT: I do not think the law requires such a statement, the Court agrees with you, but you would be in a better position before the Patent Office and before the Court if you put in that limitation because it is one thing to deal with an invention that can cause nobody any harm, quite another thing when you are dealing with medicine or a process in producing a medicine.

MR. BICKEL: Your Honor, the Patent Office specifically limited the plaintiffs, the applicant at that time to showing human transfusion tests. I call your attention—in other words, no opportunity was given to submit lesser tests. Human transfusion tests specifically were required, and we contend that is where their error lies.

Now, if you will look at the Board of Appeals
59 decision. I believe you have it separately, at page 2
of the decision. There they state:

> "Applicant has not submitted any factual evidence to establish that frozen blood when rapidly thawed by the claimed process gives a composition useful for transfusion."

And later on, on the same page, they state—excuse me—the other thing to which I am referring is the statement of the Examiner himself that tests on the order suggested by Tullis, cited to show the state of the art—and I believe your Honor has that reference—should have been presented as a showing of utility. There was no opportunity given to show other laboratory tests which had taken place to show that this would work.

THE COURT: I do not know what you mean by no opportunity was given. On page 3 of the Board of Appeals opinion it is stated it remains unexplained why some clinical evidence has not been submitted in substantiation.

MR. BICKEL: I would interpret clinical evidence, your Honor, as requiring some showing of using this upon some living creature, rather than a showing that this would work without raising the temperature of the blood.

THE COURT: Clinical evidence, I take it, means experimentation and not just a statement of opinion.

60 MR. BICKEL: The statement of opinion so-called, which is in the record of this case, is not a statement of opinion at all. It was called opinion simply because it was quoted by a man who worked for the company. The affidavit was made by a man who worked for the company to which the application had been assigned. The affidavit states that the experiment has been performed. I should read it verbatim. It says there has been a successful doing.

But I do state at this time to the Court this affidavit was not meant to imply that this has ever been used for human transfusion purposes as yet, and that affidavit did not mean to so imply.

THE COURT: Are you stating that it is not intended to be used for human transfusion purposes?

MR. BICKEL: I am stating that this application thaws blood. This thawed blood has a usefulness. That before it could be used for human transfusion there would be of necessity a requirement for further development, further testing to make certain of this. But there is no scientific reason, when viewing this application, to predict that it would not work successfully for human transfusion purposes.

THE COURT: It seems to me that you are trying to shift the burden of proof to the Patent Office. The applicant must establish he is entitled to a patent.

61 MR. BICKEL: Your Honor, I call your attention to the Supreme Court decision of Hildreth vs. Mastoras, 257 U.S. 27. This is cited on page 12 of our brief. Here we are speaking of—in that decision they are speaking of a machine. In other words, they are not dealing with a chemical compound. It says:

> "The machine patented may be imperfect in its operation; but if it embodies the generic principle, and works, that is, if it actually and mechanically performs, though only in a crude way, the important function by which it makes the substantial change claimed for it in the art, it is enough."

THE COURT: Well, I do not think it is appropriate to compare a process of this kind with a purely mechanical process.

MR. BICKEL: Your Honor, the evidence submitted, and this is actually another viewpoint of the case now, regardless of that argument the evidence submitted by the witness here shows definitely that the temperature of the blood as it is passing through this apparatus ends up at approximately 37 to 50 degrees centigrade. That testimony shows that if the speed is properly adjusted

62 there will be no scorching of the blood cells. It shows that this heat—the blood cells themselves have not risen to the heat. Now, this is not by test, this is by application of recognized scientific principles.

THE COURT: That is just the difficulty, Mr. Bickel. The Court was highly impressed by the achievements and the logic of Dr. Klotz, but nevertheless the Court cannot overlook the fact that his testimony is opinion testimony and is not based on experimentation. In other words, it is deductive logic rather than inductive logic.

MR. BICKEL: Correct, your Honor, but it does follow recognized scientific principles.

I call the Court's attention again to the Court of Customs and Patent Appeals, but I think this is a significant case. We are discussing, more or less, I know, the burden, the onus is upon the applicant, but there are reasonable grounds upon which the Patent Office may act too; they may not just on sheer speculation decide that something may not work. In the case cited at page 13 of our brief, Application of Chilowsky, 229 F. 2d 457, in that case neither the Examiner nor the Board pointed out—I am referring to page 462, your Honor—

THE COURT: What case are you referring to?

MR. BICKEL: Application of Chilowsky, 229 F. 2d 457, at page 462. If I may read briefly from the opinion:

> 63 "Neither the Examiner nor the Board pointed out any specific feature of appellant's disclosure which was definitely shown to be, or even considered to be, inoperative. The basis of the rejection seems rather to be that the apparatus may not operate, because of various difficulties which may arise when it is constructed."

And then skipping a few lines, to the conclusion of the Court:

> "Thus, in the usual case where the mode of operation alleged can be readily understood and conforms

> to the known laws of physics and chemistry, operativeness is not questioned, and no further evidence is required."

THE COURT: Now what case are you reading from?

MR. BICKEL: Application of Chilowsky, Court of Customs and Patent Appeals, 1956.

THE COURT: Is that cited in your brief?

MR. BICKEL: Yes, your Honor, at the bottom of page 13 of our brief.

THE COURT: Yes.

MR. BICKEL: And then the Court concluded at page 463 that the Patent Office had not given sufficient reason for their rejection.

Now, if the Court will search this file wrapper
64 from cover to cover you will find that no scientific
reason has ever been given in there why this wouldn't work except that the Examiner thought the cells, and I believe this is an exact quote, might be scorched. And they do not question utility except in the sense of operability, if the Court will notice. The question here is whether this machine will work. But it conforms in every respect to scientific principles. There is no reason why it would not work, and we contend that in that situation that is a sufficient showing of operability. And that is actually the question here, operability, will the thing work. And we contend further that, through the cases, we have made a sufficient showing. The Supreme Court has passed upon this, it is before the Court of Customs and Patent Appeals; I refer the Court to the other cases cited on pages 11 through 13 of the brief. And I think this is a significant case, page 14 of our brief, your Honor—and this is quite applicable to what we have here—in the center of the page we quote from Thomas vs. Michael, 166 F. 2d 944. Do you find the reference? At page 946 and page 947 the Court points out that:

> "Where the utility of a new product produced by
> a novel process is not known or apparent, a test is
> required to establish reduction to practice of that
> process. But where the utility of an old product
> 65 produced by a novel process is known, a test is
> not required to establish reduction to practice of
> that process."

Now, again, we are dealing with an old product, applying sound recognized scientific principles to it, creating no new material, and obviously not causing the effect which the Patent Office speculated would happen. That is, it is perfectly clear that they contemplated that when you apply 1100 degrees temperature to the blood, it itself is going to raise to an extremely high temperature. And the record is perfectly clear that they were contemplating something which itself is contrary to scientific principles.

The decision again of the Court of Customs and Patent Appeals in the Nelson case which was cited to you by defense counsel—I believe you have it out—points out one other important thing. This involves a matter of intermediates. Now, in the chemical sense this would be, perhaps I could explain it as a compound which itself would be useful in leading to the development of other compounds, but which of itself has no use whatsoever except as that starting point. And these types of compounds have been held to be patentable.

Now, in the present case, we are not using the device
here as a starting point for a new type of device, but yet
here we have something which is operable, accord-
66 ing to every scientific principle that is before the
Court and certainly that exists. It is a basis upon
which a very, very significant thing can be developed.

Now, specifically, I mention this: in the event of national attack, atomic attack, such as could occur, large quantities of blood are needed. They aren't needed a half an hour from the time the patient comes in, they are needed instantly. This invention, when perfected to the point of being used on human beings, could provide that instant—practically instant; one second or less—blood.

THE COURT: I do not think the Government would deny that. The Government says that you have not progressed in your experimentation far enough to be able to say that this can be done by this invention.

MR. BICKEL: But the Government does not contend that this invention will not thaw the blood. There is no contention whatsoever that this won't work.

THE COURT: The Government says that they are not sure that the blood produced by the process will not be deteriorated in the process. That is practically their position. Is that not so?

MR. ARMORE: That is correct.

MR. BICKEL: But the fallacy of their position is apparent in their argument because they assume
67 the blood will reach this high temperature. They fail to take into account the laws of science.

THE COURT: I do not want to hurry you so I will let you go on tomorrow morning.

MR. BICKEL: Your Honor, I presume that defense counsel will have some other things. This would, in essence, except for a short summary, close my argument, and then I will make that summary first thing in the morning and be done.

THE COURT: Very well. I might say to counsel, perhaps it might be helpful to them to know it, that I am going to go over all the papers tonight, that is, the application, plaintiffs' brief and the opinion of the Board of Appeals and so on.

MR. BICKEL: Thank you, your Honor.

(Thereupon, at 3:55 p.m., trial stood in recess, to reconvene October 31, 1961.)

68 UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

Civil Action No. 2997-59

The Commonwealth Engineering Company
of Ohio, and
Carl Berger,
Plaintiffs

vs.

David L. Ladd,
Commissioner of Patents,
Defendant

Washington, D. C.
October 31, 1961.

The above-captioned cause came on for further trial before the HONORABLE ALEXANDER HOLTZOFF, Judge, United States District Court for the District of Columbia.

APPEARANCES:

On behalf of the Plaintiffs:

DWIGHT F. BICKEL, ESQ.
FOLSOM E. DRUMMOND, ESQ.

On behalf of the Defendant:

JACK E. ARMORE, ESQ.
Patent Office.

69 PROCEEDINGS

THE COURT: We will resume the trial of the patent case.

THE DEPUTY CLERK: Commonwealth Engineering vs. Watson.

MR. BICKEL: Your Honor, I had but just a few closing remarks to my argument at the time we concluded.

THE COURT: Yes, I will be very glad to hear you.

MR. BICKEL: Before closing our argument on the case, I think it is very important to call one additional authority to the Court's attention which is not cited in our brief but which comes about as a result of some of the questions asked by the Court from the bench yesterday.

It appears, and very rightly so, that since this device involves the thawing of blood cells, the quick thawing of frozen blood cells, that perhaps they may be reason in the Court's mind—and I am sure from the questions there was—of concern over whether this would be, if the patent were granted, this would be advertised and sold to the public when it was not in a safe condition.

We feel that the evidence showed clearly that the blood cells would not be deteriorated. But, nevertheless, even assuming for a moment there is a possibility, as a matter
of policy it is not necessary that this public pro-
70 tection come under the patent law because here we
do not have a new chemical compound, we have an old compound and we have a biological material. This is the distinction.

You see, there is ample regulation of the sale of biological material, that is, material involving living organisms. 42 U. S. Code, Section 262, concerns the regulation of the manufacture and sale of biological products. Under that section, which is under the public health sections, your Honor, the Department of Health would have to approve the manufacture or sale of any product resulting from plaintiffs' process before it could ever be used upon human beings.

There is a case, Merck & Co. vs. Kidd, decided by the Sixth Circuit Court of Appeals, 242 F. 2d 592, in which it was held that blood plasma manufacture and sale was subject to regulation under the section of the U. S. Code which I have cited.

So, as a matter of policy, your Honor, we make the point that the Congress has specifically provided for the protection of the public in the use of materials involving living organisms such as blood and that it is our contention and we contend that the cases support this, that it is not for the patent law in that field, where there already is ample protection provided by law, it is not for the patent law to provide that protection.

71 THE COURT: You say the cases so hold. The Isenstead case does not so hold. It holds the other way.

MR. BICKEL: Your Honor, we contend that the Isenstead case, we have no disagreement with that case at all, that deals not with biological material, that deals with a chemical compound. Now, there is no such provision, you see, for the Department of Health to investigate this compound under the section of the Code that we are providing.

THE COURT: What is the section, please?

MR. BICKEL: The section of the Code is 42 U.S.C.A. Section 262. The application of this to blood plasma was decided in the case at 242 F. 2d 592. I have that here, if your Honor would like it.

THE COURT: Very well.

(The document was handed to the Court.)

MR. BICKEL: The particular portion has a mark indicated on the righthand page. The case was not a patent case, it was a personal injury case, but the point came up.

THE COURT: Very well.

MR. BICKEL: Therefore, in summary of our argument, your Honor, we feel that we have shown statutory utility within the requirements of 35 U.S.C., Section 101. We contend that based upon the cases that we cited, for

example, certainly the Hildreth vs. Mastoras case,
72 decided by the Supreme Court and actually within
the general statement of our District of Columbia Court of Appeals in Canadian American Pharmaceutical Co. vs. Coe. This case was not discussed yesterday, but it is reported at 126 F. 2d 847. That involved a new product called by the name Ensol, which was to be a cancer remedy, and the evidence showed, as the Court said—may I quote briefly from the decision?

> "It may be that some medical scientist would discourage the use of Ensol pending further tests. It is not within our function to decide and we could not assume to decide whether its use should be encouraged or discouraged."

THE COURT: What Judge wrote that?

MR. BICKEL: Your Honor, I'm sorry.

THE COURT: Those things are important sometimes.

MR. BICKEL: Yes, I know they are, your Honor. I can find it for you very quickly. May I proceed?

THE COURT: Yes.

MR. BICKEL: In the Canadian American Co. case that I have just mentioned, the Court discussed the fact that there was evidence in the case—

THE COURT: What is the citation to that case?

MR. BICKEL: 126 F. 2d 847. In that case the Court
discussed the fact that the evidence showed that the
73 particular medicine could be used and that there
was evidence that it could be used without harm, although not necessarily with curative effects, and that it might relieve pain; and then the Court cited the Hildreth vs. Mastoras case in the Supreme Court and held that since it had been proved that it worked in a sense, that there was some use for the product, that there was a sufficient showing of utility.

THE COURT: What is the Hildreth case?

MR. BICKEL: Hildreth vs. Mastoras was a case in the United States Supreme Court involving a rather crude invention which did—in other words, the product as described by the patentee was not as operable as a mechanical improvement, in the manufacture sense.

THE COURT: Is that the case that held that a slight degree of usefulness is sufficient? I do not think you need labor that point.

MR. BICKEL: It was on the question of operability, your Honor, and said that if it would work at all, that the requirement of the statute had been satisfied.

But the burden of proof here admittedly is upon the plaintiffs. However, we feel this, that there certainly are cases which tend to show that statutory utility has been proved. We have introduced evidence to show
74 that according to all of the laws of science, that
this man that we used as an expert, who certainly is well qualified, could know of, there is no reason why this process would not work, there is no reason to believe it would cause the deleterious effect that the Patent Office wondered about. The Patent Office has brought in no evidence to the contrary.

THE COURT: I wonder if that is quite accurate. The Patent Office Examiner, who is a technician, expressed one opinion. Your witness expressed the opposite opinion. Neither one performed any experiments.

MR. BICKEL: Your Honor, the Patent Office Solicitor, and I am positive I am correct in this, simply said that he wondered if it would scorch the blood cells. It is obvious from reading the file wrapper that the Patent Office continually assumed that the blood cells would reach the temperature of the outside heat that was being applied to them. Therefore—

THE COURT: I must say, quite frankly, that one of the things that surprises me about this case is that you never conducted any experiments. Now, I realize the difficulties and the expense of conducting experiments with human blood. But you were discussing the use of sheep's blood in laboratories. It seems to me that you

could have conducted a series of experiments with
75 sheep's blood to demonstrate by experimentation
instead of by a priori reasoning that the process
can be operated successfully.

Now there was another thing. You submitted an affidavit—I went through the file wrapper last night,—by a gentleman by the name of Novak, and in his affidavit there is a conclusion that experimentation has shown that this operates successfully. Well, that is of no evidentiary value unless the dates and the number of the experiments were given, how the experiments were conducted and the results of each experiment.

MR. BICKEL: You will note, your Honor—

THE COURT: That is what stands out in my mind so far as this case is concerned, the fact that there has been no attempt at experimentation.

I was very much impressed by Dr. Klotz' testimony. There is no doubt about his being an experienced as well as a theoretically learned gentleman in his field, but I notice that his opinion too is based on a priori reasoning and not on observation or experimentation. So is the Patent Office Examiner's. But why should I prefer the a priori reasoning of a partisan expert to the a priori reasoning of the Patent Office technician?

MR. BICKEL: There is one reason that I could suggest to the Court. The expert witness was able to
76 support by reference to standard known laws of
physics the bases for his decision. The Patent
Office—

THE COURT: Yes. You know, that reminds me of a book that was written around 1889 by an outstanding physicist who demonstrated by mathematical formula and the laws of physics that flight by heavier than air machines was impossible. Yet, three years later or a few years later the Wright brothers made their flight at Kitty Hawk.

So, there is a difference between a priori reasoning and reasoning based on inductive logic derived from a series of experiments.

MR. BICKEL: Yes, your Honor. Well, it seems that the issue is clearly drawn, in that event, because it is our position that this is a legal matter, just as any other matter which comes before the Court, and the rules of law and legal procedure we contend should exist in patent cases similarly to other cases.

We have cited to the Court many authorities which hold that where a process does not contravene known laws of chemistry and physics, that tests are not necessary. The requirement for testing rests upon a decision of public policy in the health field. We have shown the Court in this particular—

THE COURT: I do not mean to suggest there
77 is any rule of law requiring testing. But I have
to weigh the evidence—

MR. BICKEL: Yes, your Honor.

THE COURT: —as a matter of fact, not as a matter of law. And the absence of testing is an evidential fact that I must weigh.

MR. BICKEL: But the issue raised by the Patent Office is only one, and that is: are tests necessary. You see, there was no other ground cited by the Patent Office for rejection of these claims. And we feel that where the public's health and welfare is adequately protected by special Congressional enactments in this field, that a showing of compliance with known laws of physics and chemistry is sufficient within the law.

I have no other remarks, your Honor. Do you have any further questions?

CLOSING ARGUMENT BY COUNSEL ON BEHALF OF DEFENDANT

MR. ARMORE: May it please the Court, I would like to address myself at the outset to some of the points raised and presented by the plaintiffs' counsel, and particularly the last point or one of the last points he made with respect to the citation in 42 U.S. Code 262.

THE COURT: That is a side issue, Mr. Armore. I suggest you just confine yourself to the issues that
78 I have to decide.

MR. ARMORE: All right, your Honor.

THE COURT: That was an appeal, an argument on a homonym, so to speak.

MR. ARMORE: During the course of the argument by plaintiffs' counsel yesterday he pointed out that the disclosure of human use in the specification was in a discussion of prior methods and, therefore, he concluded that the disclosure was not necessarily limited to human use. However, I would like to indicate to the Court that the sole disclosure of—that the alleged invention, the claimed process, is supposed to be an improvement over the prior process and, therefore, obviously it is intended for the same use which is assigned to the prior process, and, furthermore, that is the only specific use disclosed in the specification.

THE COURT: I would appreciate very much a very skeletonized and brief argument on the part of Government counsel. Direct it solely to the issues involved and not any side issues.

MR. ARMORE: All right, your Honor. The utility is a statutory requirement, as your Honor knows. In cases of patent applications involving medical materials, the requirements necessary to establish utility have been set forth in Isenstead vs. Watson, and I will not belabor that point.

79 THE COURT: Have been set forth in what?

MR. ARMORE: The requirements necessary to establish utility have been set forth in Isenstead vs. Watson, and I will not belabor that case any further.

THE COURT: No.

MR. ARMORE: I think it has been discussed sufficiently.

In this case it has already been asserted and argued that the sole disclosure of utility is for human transfusion. The claimed process is directed to a compound—to a material intended to be used by a human being.

THE COURT: I am not quite clear about that, Mr. Armore. One of the things that I think is to be deplored is that the specification gives no suggestion as to what use might be made of that process, so that ostensibly it might be used either for human beings or not or for other purposes or for both.

MR. ARMORE: Your Honor, I suggest it is the position of the defendant that in effect one skilled in the art, reading the specification, would draw the conclusion that the intended purpose of the product of the claimed process is for human use, in view of the second paragraph on page 1 of the specification.

THE COURT: What inference do you draw from that?

80 MR. ARMORE: Well, the inference I draw from that is that the product of the claimed process is a medical product intended for human use and, therefore, it is subject to a showing of utility as set forth in Isenstead vs. Watson.

Furthermore, even if I were to agree with your Honor that there were no specific indication as to any particular use, as your Honor has pointed out there has been no showing with regard to any use whatsoever in any event.

THE COURT: I think we will take our usual midmorning recess at this time and let you continue after the recess.

(Brief recess.)

THE COURT: Mr. Armore, you may proceed.

MR. ARMORE: Your Honor, I will attempt to make my remarks as brief as possible.

I will merely recall to your Honor the paragraph I pointed to on page 8 of the plaintiffs' brief, trial brief, which indicates that this material which results from the claimed process has never actually been tested, it's never been tried. This in effect is nothing more than—

THE COURT: Yes, you called the Court's attention to that part of the brief in your opening argument and I have marked it.

MR. ARMORE: All right, your Honor. I had
81 indicated in my opening remarks that I would discuss the Nelson and Krimmel cases.

THE COURT: Yes, very briefly I will be very glad to get your comments on them.

MR. ARMORE: Yes, your Honor. In the Nelson case the Court of Customs and Patent Appeals was confronted with the question of patentability of claims directed to steroid intermediates, where the application showed that these intermediates can be reacted with other substances to form steroids, final product, and wherein the disclosure indicated that some of these steroids had important physiological functions. Now, the Court held that where claims are directed to intermediate compounds which are useful in preparing other compounds, some of which are known to have useful functions, useful physiological functions or other functions, sufficient utility is shown under the statutory requirement in 35 U.S.C. 101.

THE COURT: I think the only usefulness of that case so far as the issues here are concerned is the rule laid down in that case that it is not necessary to show that there be any particular degree of utility, so long as there is some utility. I think that is really the value of that case.

MR. ARMORE: Your Honor, but that rule has very limited application. It is not a general rule. It is limited only to an intermediate. That rule has to be in-
82 terpreted in the light of the facts of that situation.

THE COURT: No, I think it is a general rule. I think that is a very well reasoned opinion, but it does hold that there must be some degree of utility. There does not have to be any particular degree.

MR. ARMORE: That is correct, your Honor, there must be some degree of utility.

On the other hand, it is not inconsistent with the decision in Isenstead vs. Watson.

THE COURT: No. I do not see any inconsistency.

MR. ARMORE: Precisely. And that rule does not affect the situation presented in the particular suit at bar, which presents a set of facts corresponding to the Isenstead vs. Watson case.

As for the Krimmel case, in the Krimmel case the Court there was considering the patentability of claims directed to a class of compounds where the disclosure in the specification—

THE COURT: How do you distinguish it? Let's get the distinction between the Krimmel case and this case.

MR. ARMORE: The distinction is simply this: in the Krimmel case there was very adequate evidence by way of statistical showings of experimental —

THE COURT: I think that is the distinction.

83 MR. ARMORE: That is one of the major distinctions, yes. There was definite evidence showing tests and experimentation and the results of these tests, and these tests were considered statistically significant.

The other distinction, as I would view it in view of the defendant's view of this case, is that in the Krimmel case the disclosure was of utility, was for pharmaceutical applications, and the Court held that where there was a showing of experimental testing with respect to animals it was sufficient to satisfy the utility requirements since pharmaceutical applications is a broad generic—

THE COURT: There was experimentation there.

MR. ARMORE: There was experimentation.

THE COURT: Very well. That is the big distinction, it seems to me, between the Krimmel case and the case at bar, that there was experimentation in the Krimmel case.

MR. ARMORE: That is the major distinction.

THE COURT: Don't dilute it by giving some minor distinctions.

MR. ARMORE: I will proceed to the last point that I would like to present for the Court's consideration, and I have already touched on that point and I will only mention it very briefly for the record.

I have indicated—

84 THE COURT: Do not mention anything just for the record. If you do not think I need it, do not mention it.

MR. ARMORE: Well, I have already discussed it, so I won't mention it, your Honor.

THE COURT: What is the matter?

MR. ARMORE: That matter relates to the matter of laboratory testing. I pointed out to your Honor that there has been no evidence in the record before the Patent Office of laboratory testing, nothing in the application, and that is new evidence.

THE COURT: Very well. Thank you.

Do you wish to say anything in reply?

MR. BICKEL: I believe we have stated our case, your Honor.

85 OPINION OF THE COURT

THE COURT: This is an action against the Commissioner of Patents under 35 United States Code 145 for an adjudication that the plaintiffs are entitled to a patent on an application that the defendant has rejected.

The application was filed by Carl Berger and assigned to the plaintiff Commonwealth Engineering Co. of Ohio on July 27, 1953, and is numbered 370533. It is entitled "Reconstitution of Frozen Biological Cellular Material". It involves a process for rapidly thawing and melting frozen blood. The specific process, in a general way, consists of passing the frozen blood through an elongated tube, which is heated to a high temperature, but the temperature of which gradually decreases to a temperature at the discharge end which it is desired the blood to reach.

The specification does not indicate the purpose or purposes for which this process is to be used. Testimony introduced in behalf of the plaintiff through an expert witness is to the effect that it may be used in connection with the making of medical diagnoses in medical laboratories, as well as in connection with blood transfusion in human beings, and that it may be employed both in connection with human blood and with animal blood
86 inasmuch as animal blood is used in certain tests in connection with medical science.

The application was rejected on the ground that the alleged invention was lacking in utility. Thus, the Examiner in his answer before the Board of Appeals stated:

> "The examiner is of the opinion that high temperatures denature blood, thus making it unfit for transfusion purposes. In order to rebut the position taken by the Examiner, applicant has presented two affidavits. These affidavits are nothing more than opinion affidavits in that they set forth nothing more than conclusions."

The Examiner concluded:

> "In the absence of tests establishing the utility of applicant's process the rejection for lack of utility is considered proper."

The Board of Appeals, in its opinion, pointed out that:

> "Appellant has not submitted any factual evidence to establish that frozen blood when rapidly thawed by the claimed process gives a composition useful for transfusion."

It might be added that the plaintiff has not submitted any factual evidence to establish that frozen blood
87 when rapidly thawed by the claimed process gives a composition useful for any purpose whatsoever.

And, again, the Board of Appeals states:

> "The Examiner has given sound scientific reasons for rejecting the claims for lack of utility or inoperativeness for the intended purpose. Appellant has not shown wherein the Examiner is in error and has thus far failed to prove his case."

Accordingly, the Board of Appeals affirmed the rejection.

It is, of course, well established that two elements must exist in order to justify the issuance of a patent on the product of the inventive faculty: first, novelty: and, second, usefulness.

We are dealing here with the element of usefulness. 35 United States Code 101.

It is true, as is argued by counsel for the plaintiffs and as was held in a thorough and well considered opinion by the Court of Customs and Patent Appeals in the application of John A. Nelson, 280 F. 2d 178, that a high degree of usefulness need not be established, all that is needed is some degree of usefulness. In this case, however, the Patent Office held that there was

no usefulness whatever in any degree, on the
88 ground that the process will destroy the usefulness
and the value of the very product which it is designed to produce by ruining its vital properties. Consequently, on that basis, the process is entirely lacking in utility.

In this connection, it might be useful to advert briefly to the question as to what constitutes utility within the meaning of the patent law. The Circuit Court of Appeals for the Eighth Circuit in Besser v. Merrilat Culvert Core Co., 243 F. 611, 612, held, in connection with defining the term useful as applied to a machine:

> "The term useful, as contained in the patent law when applied to a machine, means that the machine will accomplish the purpose practically when applied in industry. It is to be given a practical and not a speculative meaning. It means that the machine will work and accomplish the purposes set forth in the specifications."

This Court held in Isenstead v. Watson, 157 F. Supp. 7, that the term utility is a broad term and implies, among other things, capacity to perform the function or attain the result claimed by the applicant in his disclosure. It further held that, in connection with a composition of matter, the test of utility is whether the invention will attain the purpose and will operate as disclosed
89 and claimed by the inventor.

Similarly, in connection with an invention consisting of a process or a method, the term utility must necessarily mean whether the process will operate as claimed and will produce the result intended by the inventor.

In this case, the Patent Office held that such a result will not be produced. The plaintiff sought to overcome the opinion of the Patent Office on this technical scientific subject by adducing contrary opinions of other technicians. Ordinarily, in such a situation, the Court should sustain the ruling of the Patent Office since it is presumptively correct. It has been said time and time again that a great weight must attach to the findings of the Patent Office, especially on highly technical matters.

Under the circumstances, in this state of the record, it would seem that some experimentation is necessary to demonstrate the error of the opinion of the Patent Office. One a priori opinion as against another a priori opinion is not sufficient.

It is argued in behalf of the plaintiff that it should not be necessary to show that the process will operate successfully with human blood as against animal blood. This argument is, however, irrelevant because it has not been shown by experimentation that this invention
90 will accomplish the desired objective even with
animal blood.

It may be repeated that it is sought to overcome the impartial opinion of the Patent Office by a partisan opinion of the plaintiff's expert, without demonstrating the error or alleged error of the Patent Office by actual reduction to practice or even by laboratory experiments. To be sure, from a technical legal standpoint the filing of the application constitutes a reduction to practice, but when the Patent Office expresses a technical opinion that a process would not operate as claimed or would not result in the product desired to be obtained by the process, in order to overcome this conclusion some proof must be submitted and not merely another expert's a priori opinion, especially a partisan expert. By referring to the expert as partisan the Court does not mean to imply any criticism. The Court was impressed with the experience and the attainments of the plaintiff's expert. His opinion, however, was reached entirely on a priori reasoning, and it must be realized that partisanship is part of the unconscious make-up of every human being.

Under those circumstances, the Court is of the opinion that the Ruling of the Patent Office has not been sufficiently overcome to justify the Court in reaching the conclusion that the Patent Office erred.

In this connection, it is interesting and significant
91 to refer to some of the proceedings in the Patent Office as contained in the file wrapper. In his first action the Examiner concluded:

> "The claims are rejected for lack of utility in the absence of clear convincing scientific proof that the composition produced by applicant's process is safe, effective, reliable for the purpose set forth in the specification."

Obviously, this might well have been construed as an invitation to submit some proof, but it seems to have been ignored by the plaintiff.

In a later action, found on page 48 of the file wrapper, the Examiner again stated:

> "The claims are again rejected for lack of utility. There has been no showing made to the effect that the high temperature that applicant uses would not cause denaturation of the blood proteins due to localized heating."

A similar statement was made by the Examiner in a still later action, found on page 64 of the file wrapper.

Then, finally, the plaintiff submitted an affidavit to the Patent Office. That affidavit was made by the
92 Chairman of the Board of the plaintiff corporation. It is very general in its nature and it states what the inventor has found. No affidavit was submitted from the inventor or from anyone else giving any details.

Finally, another affidavit was submitted, sworn to by one Leo J. Novak, Vice-President in charge of research and development for the plaintiff corporation. He stated:

> "Frozen blood cells reconstituted in accordance with applicant's invention have been used and found to be satisfactory."

Such a general conclusion is of no value as evidence. If there had been experimentation in the laboratory, those experiments should have been summarized; if there had been use in actual practice, such uses should likewise have been summarized.

The plaintiff strongly relies on the recent decision of the Court of Customs and Patent Appeals in the case of In Re Krimmel, 130 U.S.P.Q. 215, not yet reported officially. That case is clearly distinguishable, however, because there a certain amount of experimentation had been conducted successfully, and the Court held that this was sufficient to show the utility of the alleged invention there involved.

The foregoing discussion necessarily leads to the conclusion that no error has been shown in the ruling 93 of the Patent Office that the invention is lacking in utility.

The Court might well, however, in addition, refer to its opinion in Isenstead v. Watson, 157 F. Supp. 7, in which we suggested that:

> "Great care and scrutiny should be particularly taken in connection with applications for medical patents. While the granting of a patent does not legally constitute a certificate that the medicine to which it relates is a good medicine and will cure the disease or successfully make the test which it was intended to do, nevertheless the granting of such a patent gives a kind of official imprimatur to the medicine in question on which as a moral matter some members of the public are likely to rely."

These remarks are equally applicable to a process intended for medical use.

Accordingly, judgment will be rendered on the merits in favor of the defendant dismissing the complaint.

The Court is indebted to both counsel for a very able and interesting presentation of this case.

Counsel for the Patent Office will submit proposed findings of fact and conclusions of law and judgment.

MR. ARMORE: Yes, your Honor.

(Thereupon, the trial stood concluded.)

94 CERTIFICATE OF COURT REPORTER

I, Gerald Nevitt, Official Court Reporter, certify the foregoing 93 pages constitute the official transcript of proceedings in the afore-captioned cause.

In Witness Whereof, I have affixed my signature this 25th day of November, 1961.

/s/ Gerald Nevitt

• • • •

FINDINGS OF FACT

1. This is an action brought under Section 145 of Title 35 United States Code, in which plaintiff Commonwealth Engineering Company of Ohio, assignee, and plaintiff Carl Berger, applicant, of application for patent Serial No. 370,533, filed July 27, 1953, entitled "Reconstitution of Frozen Biological Cellular Material", sought to have the Court authorize the defendant, the Commissioner of Patents, to grant to plaintiffs a patent containing claims 17, 24, 25 and 26 of that application.

2. The specification of the application at bar states that the invention relates to a process for reconstituting frozen blood cells, by rapidly thawing and melting frozen blood, which consists of passing the frozen blood through an elongated tube heated to a high temperature (250°C. to 1100°C.) at the entrance, gradually decreasing the temperature to from 37°C. to 50°C. at the discharge end, and collecting the cells in an isotonic solution having substantially the same temperature as the thawed cells.

3. The specification does not indicate the purpose or purposes for which this process is to be used.

4. Claim 24 at issue, which is representative, as set forth in paragraph 16 of the complaint, reads as follows:

> A process for the reconstitution of frozen blood cells which consists in passing the same through an enclosure having a temperature gradient from the entrance to the exit of between 1100°C and 250°C at said entrance and 37°C to 50°C at said exit, the temperature decreasing substantially uniformly therebetween, said blood cells entering and passing through said temperature gradient enclosure within approximately one to two seconds to thaw the same quickly, and thereafter collecting the resultant thawed cells in an isotonic liquid having substantially the same temperature as the thawed cells.

5. The application claims were rejected on the ground that the alleged invention was lacking in utility. The Patent Office tribunals were of the opinion that high temperatures denature blood, making it unfit for transfusion purposes, and that in the absence of factual evidence of tests establishing that frozen blood, when rapidly thawed by the claimed process, gives a composition useful for transfusion, the statutory requirement for usefulness (35 U.S.C. 101) is lacking.

6. Plaintiffs sought to overcome the opinion of the Patent Office on this technical scientific subject by adducing contrary opinions of other technicians, and by the testimony of an expert witness to the effect that the product of the process may be used in making medical diagnoses in medical laboratories, as well as in connection with blood transfusions in human beings, and that it may be employed both in connection with human blood and with animal blood.

7. Plaintiffs have not submitted any factual evidence to establish that frozen blood when rapidly thawed by the claimed process gives a composition useful for any purpose whatsoever.

8. In this state of the record, some experimentation is necessary to demonstrate the error of the opinion of the Patent Office. One a priori opinion, as against another a priori opinion, is not sufficient.

9. No error has been shown in the ruling of the Patent Office that the invention is lacking in utility.

CONCLUSIONS OF LAW

1. It is well established that two elements must exist in order to justify the issuance of a patent on the product of the inventive faculty: first, novelty: and second, usefulness.

2. Utility, within the meaning of 35 U.S.C. 101, is a broad term and implies, among other things, capacity to perform the function or attain the result claimed by the applicant in his disclosure. Isenstead v. Watson, 157 F. Supp. 7.

3. The test for utility, in connection with a composition of matter, is whether the invention will attain the purpose and will operate as disclosed and claimed by the inventor. Isenstead v. Watson, 157 F. Supp. 7.

4. The term utility, in connection with an invention consisting of a process or method, necessarily means whether the process will operate as claimed and will produce the result intended by the inventor.

5. A holding by the Patent Office that a claimed process has no usefulness whatever on the ground that it will destroy the very product which it is designed to produce by ruining its vital properties, should, in the absence of some experimentation to demonstrate the error of the opinion of the Patent Office, be sustained by the Court since it is presumptively correct.

6. Great weight must attach to the findings of the Patent Office, especially on highly technical matters.

7. One a priori opinion as against another a priori opinion is not sufficient to demonstrate error in the opinion of the Patent Office.

8. Although from a technical legal standpoint, the filing of a patent application constitutes a reduction to practice, when the Patent Office expresses a technical opinion that a process will not operate as claimed or will not result in the product desired to be obtained by the process, some proof must be submitted, and not merely another expert's a priori opinion, in order to overcome this conclusion.

9. General conclusions, set forth in affidavits submitted during the proceedings in the Patent Office, are of no value as evidence.

10. The following remarks in the Court's opinion in Isenstead v. Watson, 157 F. Supp. 7, are equally applicable to a process intended for medical use:

> "Great care and scrutiny should be particularly taken in connection with applications for medical patents. While the granting of a patent does not legally constitute a certificate that the medicine to which it relates is a good medicine and will cure the disease or successfully make the test which it was intended to do, nevertheless the granting of such a patent gives a kind of official imprimatur to the medicine in question on which as a moral matter some members of the public are likely to rely."

11. Claims 17, 24, 25 and 26 are unpatentable.

12. Plaintiffs are not entitled to a patent containing any one of claims 17, 24, 25 and 26, set forth in paragraph 16 of the complaint.

13. The complaint should be dismissed.

Judge

December , 1961

* * * *

JUDGMENT

This action came on to be heard at this term, and thereupon upon consideration thereof, it is this day of , 1961

ADJUDGED that the complaint be and it is hereby dismissed, with costs against the plaintiff.

Judge

I hereby certify that a copy of each of the foregoing proposed FINDINGS OF FACT, CONCLUSIONS OF LAW and JUDGMENT were handed today, November 28, 1961, to the attorneys for the plaintiffs Toulmin & Toulmin, Pennsylvania Bldg., Washington, D. C.

/s/ C. W. Moore
Solicitor

Filed 1/11/62

* * * *

NOTICE OF APPEAL TO COURT OF APPEALS

Notice is hereby given that the Commonwealth Engineering Company of Ohio and Carl Berger, plaintiffs above named, hereby appeal to the United States Court of Appeals for the District of Columbia Circuit from the final judgment entered in this action on November 30, 1961.

Respectfully submitted,

Toulmin & Toulmin

By /s/ H. A. Toulman, Jr.
D. F. Bickel
Attorneys for Appellants
Pennsylvania Building
Washington, D. C.

PLAINTIFFS' EXHIBIT

NUMBER (Series of 1948)	APPEAL NO. 59-69
370533	Dated
Div. 59-43	Civil Action No. 299759

Name: Carl Berger — Assigned to The Commonwealth Engineering Company of Ohio, Dayton, Ohio, a Corporation of Ohio; of Dayton; State of Ohio.

Invention: Reconstitution of Frozen Biological Cellular Material.

TITLE APPROVED

....

Examiner

ORIGINAL

Application Filed Complete — July 27, 1953

This is to certify that annexed hereto is a true copy from the records of the United States Patent Office of File Wrapper and Contents of the file identified above.

By authority of the ACTING
COMMISSIONER OF PATENTS

[SEAL]

/s/ W. G. Lanham, Jr.
Certifying Officer

Date: March 14, 1961

NUMBER (Series of 1948)
370533
Div. 59-43

APPEAL NO. 59-69
Dated
Civil Action No. 299759

Name: Carl Berger — Assigned to The Commonwealth Engineering Company of Ohio, Dayton, Ohio, a Corporation of Ohio: of Dayton: State of Ohio.

Invention: Reconstitution of Frozen Biological Cellular Material.

TITLE APPROVED

....
Examiner

ORIGINAL

Application Filed Complete — July 27, 1953

PARTS OF APPLICATION FILED

Petition, Specification, Ooath, First Fee $30,
1 Sheets Drawings — July 27, 1953

Examined and passed for Issue.................................., 19........
.... Exr. Div...
Notice of Allowance.., 19........
Final Fee.., 19........
Attorney: TOULMIN & TOULMIN, 308 West First Street, Dayton, Ohio.
Associate Attorney ....
No. of Claims Allowed........... Print Claims...........................
in O. G. Class....................................
Division of App., No.............., filed..............................., 19......
Patent No........................., Granted ...., 19......

This invention relates to the reconstitution of frozen biological material and particularly to the reconstitution of frozen blood cells.

Previous methods for the reconstitution of frozen biological cellular material to render it suitable, for example, for human use have involved the heating of the cells in slow increments. Thus red blood cells are slowly heated, usually being held for a period of time at one temperature condition, then raised to a slightly higher temperature condition and so one until the desired temperature of 37° C is attained.

The processes referred to above are not only slow but tend to produce de-naturation within the cell as the temperature rises, this condition being occasioned as deleterious reactions occur within the corpuscle due to the increased activity thereof as the temperature rises.

It is accordingly a primary object of the invention to describe a novel method for the rapid reconstitution of frozen biological cellular material.

It is a particular object of this invention to describe a novel method for the reconstitution of frozen red blood cells.

It is a further object of this invention to describe a method for the reconstitution of frozen red blood cells which mehod conditions the cells for immediate use.

In the practice of the invention a long tube surrounded by heating coils is provided at one end with funnel means and at the other end with a receiver having a suitable liquid, as an isotonic solution, therein. The frozen cellular material which may be in discrete cluster or individual cell form is then passed through the funnel, the temperature channel defined by the heated tube and is caused to come to rest in the liquid of the receiver.

The cellular material may simply be dropped through the apparatus: generally however it will be found desirable to pass the cells through at a relatively high velocity and for this purpose the inert gases such as nitrogen and argon are most suitable as carriers or suspension media for the frozen cells.

In the preferred embodiment a temperature differential exists across the tube defining the temperature channel; the temperature is greatest at the entrance to the tube and decreases gradually to a temperature at the entrance to the receiver which is only slightly greater than the temperature of the liquid therein. Accordingly since the flow velocity will normally be substantially constant the heat pick-up by the cells is greatest when the cell is in the most frozen condition.

The cells are constituted largely by an aqueous medium surrounding a central nucleus and as the heat quickly penetrates the outer cell wall the material surrounding the central nucleus will first be liquified and accordingly the cells will tend to adopt individual motions of their own. This is important as the cells may tend to cluster together and the motion imparted by the fluid condition assists in separation into individual cells. This separation is in turn of importance as it exposes each of the cells individually to the action of the heat and accordingly each is heated uniformly and quickly from all sides.

A most suitable liquid for the receiver is one in which it is customary to store blood cells immediately prior to use. Thus an isotonic-saline solution for example is suitable; such a solution may contain distilled water and about 0.9 percent of salt (Nacl).

The invention will be more fully understood by reference to the following detailed description and accompanying drawing wherein the single figure of the drawing illustrates apparatus useful in a preferred embodiment of the invention.

Referring to the drawing the numeral 1 indicates a long narrow metal tube closed at the lower end by a flask 3 heat insulated therefrom, and provided at the upper end with a wall 5 having therein a funnel 7. The flask and funnel are if desired connected in the apparatus to be conveniently separated from the tube for cleaning and removal of the reconstituted material; the insulating ring 4 of resilient material, as rubber, may thus serve as a union for the tube and flask.

An electrical resistance heating coil 9 having leads 11, 11 connected to a source of power (not shown) surrounds the tube 1, the coil being suitably provided with insulation to prevent electrical contact with the tube. A layer of insulating material 13 surrounds the outer side of the coil.

The coil 9 has a concentration of turns at its upper end and the concentration gradually decreases to a few turns at the lower end adjacent flask 3. Thus with a given value of current flowing through leads 11, 11 the heat applied to the tube will be greater at the upper end and differential heating of the tube is assured. The particular manner of achieving the differential heating is however not a critical factor and other apparatus known to the art may be employed.

The flask 3 is partially filled with an isotonic solution 15 for receipt of cell particles 17 passing through funnel 7 and the temperature channel 19 defined by the tube 1.

The upper wall 5 is provided with an opening 21 and when an inert gas such as nitrogen is employed to carry the cells into the temperature channel the pressure developed by the rising nitrogen will cause a check valve 23 in the line 25 to open permitting the slow escape of the gas. When using gas to inject the cells the pressure should be sufficient to insure that the cells will be given sufficient velocity to carry them into the solution 15. This prevents any cells being carried toward the opening 21 by the rising nitrogen.

Injecting the cells under pressure is advantageous also in preventing cluster formation for those clusters which may tend to form are broken up by the impact of the cells with the liquid surface.

When the frozen material is simply dropped through the temperature channel as indicated in the drawing no provision need be made to maintain the liquid 15 at the desired temperature condition if the surroundings are at body temperature: however where an inert gas is employed which is at a lower temperature than the liquid, or where the surroundings are below body temperature the flask 3 should be gently heated to maintain the required temperature.

The lability and the size of the particles which is normally small will vary slightly from sample to sample but these factors are ordinarily of less importance than the original temperature condition of the particles and accordingly the latter governs the choice of tube length, temperature gradient and specific temperatures employed as well as the velocity to be imparted to the particles in their descent.

In the employment of the apparatus described for the reconstitution of frozen blood cells in accordance with the method of invention the saline (isotonic) solution is suitably maintained at a temperature of about 37°C. which is approximately the temperature to which the cells are to be raised.

The cells themselves may have been maintained at any of several temperatures in storage varying from zero degrees centigrade down to as low as minus 79°C., for example. The temperature of the cells, the temperature and length of traverse of the tube, and the velocity of passage of the particles are however correlative factors each of which may be individually controlled to bring the particles uniformly to a temperature of about 33°C.—

36° C. just prior to their entry into the isotonic solution. The heat flux through the tube together with the tumbling action generated in the cells as liquifaction occurs gives rise to uniformity of temperature in the cell bodies; the solution itself of course assists in completing the temperature rise and in attaining uniformity of temperature.

The extremely rapid activation of the cells (as low as a matter of a second or two) which inhibits deleterious reactions within the cell, the simplicity of the inexpensive apparatus required, the utility of the method and apparatus for various types of particles, the ability to maintain particle temperature always below that of the desired end temperature in tube traverse, and the uniformity of heating of the particles in the tube itself are prime factors in the inventive concept.

In specific application the blood cells may be in the frozen condition at a temperature of about 0°c. The temperature across the inlet of a 4″ diameter tube may be 250° c. and that at the outlet about 50° c; a tube length of about 18 feet is suitable to raise the temperature of the cells to the desired degree in a gravity drop prior to their entry to the isotonic solution (37° c). The time of descent of the cells under such condition will be slightly more than one second and less than two seconds.

Where a velocity is imparted to the cells and an inert gas is employed to carry the same the temperature gradient may be as high as 1000° c, that is 1100° c at the entrance and about 37° c at the exit of the tube. The only limitation between time and temperature in this connection is that the velocity be sufficiently high to prevent scorching of the cells.

The term 'rapid heating' as employed herein and the appended claims is intended to convey the meaning that the heating time is of the order of seconds usually only one or two seconds for a gravity drop and less than a second for a velocity drop. This is necessary to prevent the occurrence of deleterious reactions normally present with slow heating. This is in direct contrast to the prior art procedure wherein long periods of time, measurable in whole minutes, are employed for reconstitution of the cells.

It will be understood that this invention is susceptible to modification in order to adopt it to different usages and conditions and accordingly, it is desired to comprehend such modifications within this invention as may fall within the scope of the appended claims.

APPLICATION FOR UNITED STATES PATENT

Oath, Power of Attorney, and Petition

9117

I, Carl Berger, being duly sworn depose and say that I am a citizen of the United States residing at Dayton in the County of Montgomery and State of Ohio, whose Post Office address is in care of:

The Commonwealth Engineering Company of Ohio
1771 Springfield Street, Dayton, Ohio

that I have read the foregoing specifications and claims and I verily believe myself the original, first, and sole inventor of the invention or discovery in Reconstitution of Frozen Biological Cellular Material described and claimed therein; that I do not know and do not believe that this invention was ever known or used before my invention or discovery thereof, or patented or described in any printed publication in any country before my invention or discovery thereof, or more than one year prior to this application, or in public use or on sale in the United States for more than one year prior to this application; that this invention or discovery has not been patented in any country foreign to the United States on an application filed by me or my legal representatives or assigns more than twelve months before this application; and that no application for patent on this invention or discovery has been filed by me or my representatives or assigns in any country foreign to the United States, except as follows:

And I hereby appoint TOULMIN & TOULMIN (the sole member of which is Harry Aubrey Toulmin, Jr.) **REGISTRATION NO. 11,346, WHOSE POST OFFICE ADDRESS IS 308 WEST FIRST STREET, DAYTON, OHIO,** my attorneys with full power of substitution and revocation, to prosecute this application, to sign the drawings and to transact all business in the Patent Office connected therewith.

WHEREFORE I pray that Letters Patent be granted to me for the invention or discovery described and claimed in the foregoing specification and claims, and I hereby subscribe my name to the foregoing specifications and claims, oath, power of attorney, and this petition, this 16th day of July, 1953.

/s/ Carl Berger
Inventor

State of Ohio)
County of Montgomery) ss

Before me personally appeared Carl Berger to me known to be the person described in the above application for patent, who signed the foregoing instrument in my presence, and made oath before me to the allegations set forth therein as being under oath, on the day and year aforesaid.

SEAL

/s/ Helen Schuler
Notary Public

In and for Montgomery County, Ohio
My Commission Expires June 27, 1955

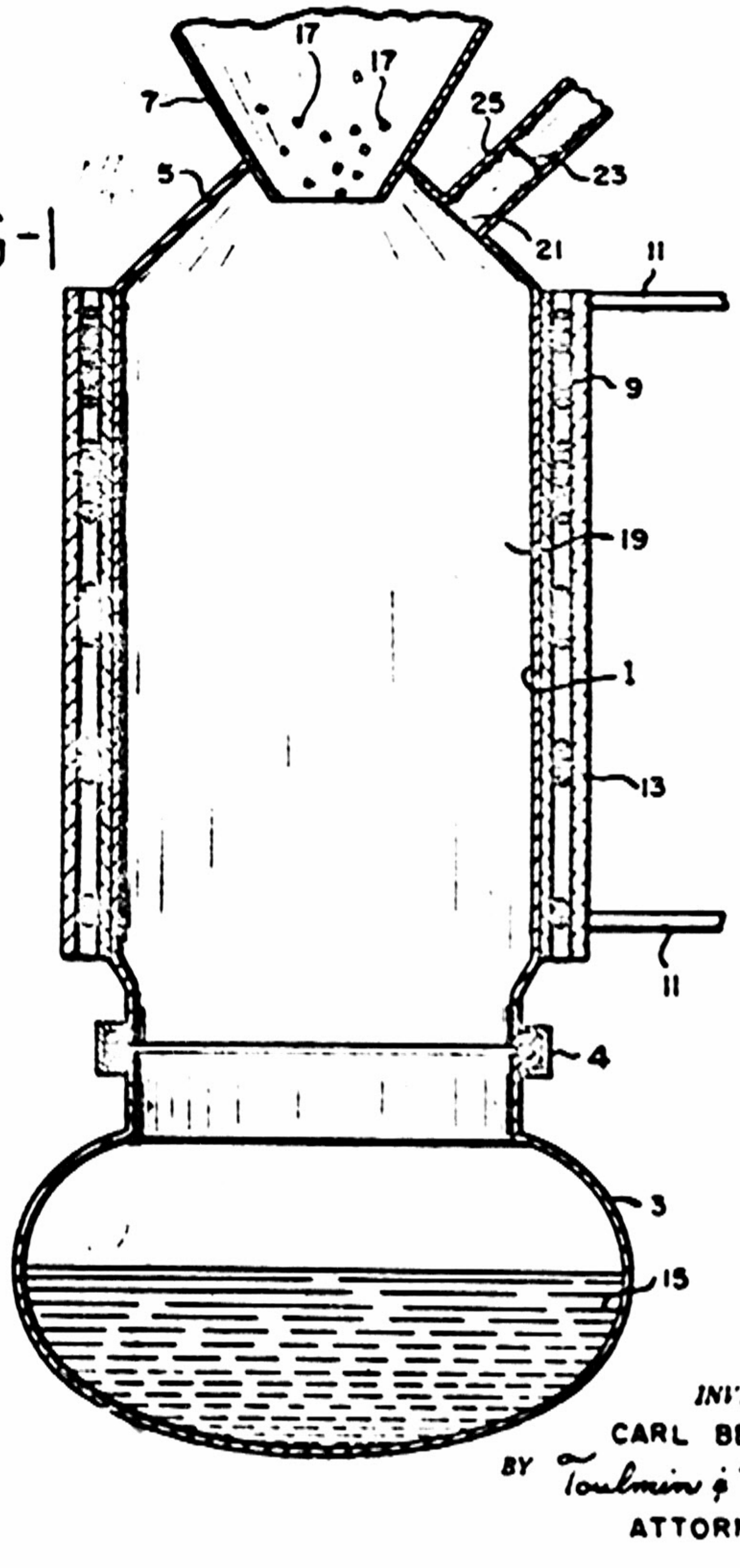
This form may be executed only when attached to a complete application as the last page thereof.

Approved Single Signature Form
Sole Inventor, or
Joint Inventor.
(No. 1250)

370533

PRINT OF DRAWING AS
ORIGINALLY FILED

FIG-1



INVENTOR
CARL BERGER
BY Toulmin & Toulmin
ATTORNEYS

DEPARTMENT OF COMMERCE
United States Patent Office
Washington

Paper No. 3

Mailed July 14, 1954, Pat. Div. 43

Applicant: Carl Berger
Ser. No. 370,533
Filed July 27, 1953

For RECONSTITUTION OF FROZEN BIOLOGICAL CELLULAR MATERIAL

Toulmin & Toulmin
308 West First Street
Dayton, Ohio

Please find below a communication from the EXAMINER in charge of this application.

/s/ Robert C. Watson
Commissioner of Patents

This application has been examined.

References applied:

Culpepper et al.	2,605,502	Aug. 5, 1952	18/8A
Clark	2,166,207	July 18, 1939	75/34 xr
Arnold	2,122,241	June 28, 1938	13/22
Gilbert	2,044,680	June 16, 1936	23/293A

Strumia—Science, Vol. 110, Oct. 14, 1949, pp. 398 and 399. (Copy in Patent Office Sci. Libr.) (167-74H)

Luyet—Freezing and Drying, 1952, Hafner Publishing Co., Inc., N.Y., pp. 77 to 79 and 84 (date of public knowledge June 1951).

Claim 1 is rejected as fully met by Strumia who shows the process for the reconstitution of frozen biological cellular material which involves rapidly heating the cellular material to a uniform temperature condition.

Claims 2 to 17 are rejected as unpatentable over Strumia and Luyet taken with Arnold. Strumia and Luyet teach the reconstitution of frozen blood by rapidly heating the blood. Luyet teaches the use of nitrogen to suspend blood. Arnold discloses an apparatus similar to applicant's useful for heating various substances. In view of this art no invention is seen in rapidly thawing frozen blood in a heating apparatus similar to that shown by Arnold.

Claims 18-20 are rejected as substantially met by and unpatentable due to the breadth of the claims over any one of the above cited apparatus combinations. Each of the above cited patents show heated tubes having a supply source thereabove and a receiver therebelow. It is to be noted that Clark specifically states page 3, column 2, lines 5-11 that heating is regulatable along the section of the tube.

The claims are further rejected as being unduly multiplied. About a half-dozen claims are all that appear necessary to adequately cover the subject matter of the alleged invention. The presence of so many claims serves to obscure, rather than point out the alleged invention. Rule 75 states that the claims should be restricted to one unless they differ substantially from one another.

Claims 1 to 17 are rejected as failing to properly define the alleged invention since they are too broad, indefinite and functional in the expressions "rapidly heating", "uniform temperature condition", "temperature sufficient to substantially thaw", "in a time on the order of seconds" and "cell velocity sufficient to substantially thaw". The exact temperature and time limitations should be set forth in the claims.

The claims are rejected for lack of utility in the absence of clear, convincing, scientific proof that the composition produced by applicant's process is safe, effective and reliable for the purpose set forth in the specification.

No claim is allowed.

/s/ (illegible)

Acting Examiner

SRosen/ebc

DEPARTMENT OF COMMERCE
United States Patent Office
Washington

Paper No. 5

Mailed May 28, 1956, Pat. Div. 43

Applicant: Carl Berger
Ser. No. 370,533
Filed July 27, 1953

For RECONSTITUTION OF FROZEN BIOLOGICAL CELLULAR MATERIAL

Toulmin & Toulmin
308 West First Street
Dayton, Ohio

Please find below a communication from the EXAMINER in charge of this application.

/s/ Robert C. Watson
Commissioner of Patents

Responsive to amendment filed January 3, 1955.

Claims 3, 6, 9, 10, 12, 14, 15 and 17 are rejected as failing to properly define the alleged invention. Claims

3 and 6 are incomplete in that they do not set forth the diferential temperatures of the channel. Claims 3, 9, 10 and 12 are too broad and indefinite in the expression "biological cellular material". The only material disclosed in the specification is blood. Claim 3 is functional in the expression "rapidly heating". The claims are indefinite in that they do not set forth the condition of the gas, i.e. liquid, gas or solid. In claim 12 the word—flux, should be inserted after "lower". Claims 14 and 15 are functional in the expression "cell velocity sufficient to substantially thaw" and "cell velocity sufficient to inhibit scorching". Claim 17 should be amended to show that the cells are first treated at the higher temperature.

The claims are again rejected for lack of utility. There has been no showing made to the effect that the high temperatures that applicant uses would not cause denaturation of the blood proteins due to localized heating.

Clear issues as to patentability having been reached this rejection is made FINAL.

/s/ D. Arnold
Examiner

SRosen: dlr

DEPARTMENT OF COMMERCE
United States Patent Office
Washington

Paper No. 7

Mailed October 24, 1956. Pat. Div. 43

Applicant: Carl Berger
Ser. No. 370,533
Filed July 27, 1953

For RECONSTITUTION OF FROZEN BIOLOGICAL CELLULAR MATERIAL

Toulmin & Toulmin
308 West First Street
Dayton, Ohio

Please find below a communication from the EXAMINER in charge of this application.

/s/ Robert C. Watson
Commissioner of Patents

Responsive to amendment filed Oct. 3, 1956.

The omission from the second line, third paragraph of page 8 of the specification should be remedied.

It is noted that applicant has not discussed the rejection for lack of utility.

The amendment submitted Oct. 3, 1956 has been carefully considered, but it has not been entered. The newly presented claims would not place this case in better condition for appeal. These newly presented claims do not specifically set forth what biological cell is being treated. As stated in previous Office actions the claims should be restricted to blood only since that is the only biological cell disclosed in the specification. The limitation "filled with inert gas", appearing in claim 22 is misleading in that oxygen has not been excluded from the system. The velocity as set forth in claim 23 is still considered functional.

No claim is allowed.

Claims 3, 6, 9, 10, 12, 14, 15, and 17 remain in this application.

Claims 21 thru 23 have not been entered.

A proper response to the final rejection of May 28, 1956 should be made in order to avoid the issue of abandonment.

s/ D. Arnold
Examiner

S. Rosen; f

The Evaluation of Chemical De-icing Solutions

By Carl Berger

Removal of ice is a critical problem in air and land transportation and in overhead power lines. The author has provided data of technical and economic value on the efficacy of de-icing solutions used in removal of frost or ice films.

The removal of frost or ice films has been and is a critical problem in air and land transportation, overhead power lines, and other situations in which hazardous and costly icing may occur.

A number of approaches have made considerable inroads on the problem and have provided the needed solution to some of the above difficulties. Among these approaches are devices such as the rubber boot on airplane wings, the circulation of warm gases between layers of glass pane to provide better visibility, thermal devices, and chemical sprays. An interesting description of chemical and mechanical methods of de-icing was given by [illegible] in the *Aero Digest*.[1]

Chemical sprays have been employed in the past for de-icing purposes, and their current use continues to be vital in the abovementioned applications. The comparative potency of various de-icing solutions is therefore of much technical and economic value.

From a practical point of view there are a number of factors which influence the effectiveness of a de-icing spray. These can be expressed as:

$$E = f(A, T_s, T_f, C, M) \quad (1)$$

where:

E = de-icing effectiveness,
A = the surface area of ice or snow exposed to de-icing liquids,
T_s = temperature of the de-icing solvent or solution,
T_f = temperature of ice or snow,
C = a variable representing a combination of wetting power and ice dissolution potential of the test fluid, and
M = time that de-icing solution is in contact with ice or snow.

NOTE—DISCUSSION OF THIS PAPER IS INVITED [illegible]

TABLE I.—[illegible]

[illegible]	[illegible]	[illegible]	[illegible]
Amyl alcohol	[illegible]	[illegible]	[illegible]
Acetone	[illegible]	[illegible]	[illegible]
Methyl Cellosolve	[illegible]	[illegible]	[illegible]
[illegible]	[illegible]	[illegible]	[illegible]
Butanol	[illegible]	[illegible]	[illegible]
Butyl Cellosolve	[illegible]	[illegible]	[illegible]
Cellosolve	[illegible]	[illegible]	[illegible]
[illegible]	[illegible]	[illegible]	[illegible]
Ethyl Carbitol	[illegible]	[illegible]	[illegible]
Glycerol	[illegible]	[illegible]	[illegible]
Isopropyl alcohol	[illegible]	[illegible]	[illegible]
[illegible]	[illegible]	[illegible]	[illegible]

The symbols have the following significance:

S = total volume in ml of de-iciated fluid [illegible]
The deviation of these values [illegible] the volume of water remaining in the [illegible] variation was within the desired degree of [illegible]
ΔS = amount of dissolved ice removed in terms of [illegible]
C = dissolution potential of de-icing fluid expressed as [illegible] min × 100.
V = viscosity of fluid being tested expressed as:
1 = mobile
2 = viscous
3 = very viscous
K = qualitative expression of how fast test material spreads [illegible]
1 = fast spreading
2 = average spreading
3 = slow spreading
H = qualitative expression of adherence of mixture [illegible] where:
1 = good adherence
2 = average adherence
3 = poor adherence

In order to establish a useful comparative criterion of ice dissolution ability, it was necessary to reduce the number of variables.

The variable A certainly would have many different values dependent on the nature of the deposited ice or the particular frost surface. We therefore eliminated this variable by the use of a standard ice surface of given area. T_s and T_f may be fixed at given values depending on the practical situation one is attempting to simulate on a laboratory basis, and M may be designated arbitrarily. The fixing of A, T_s, and T_f, and M leaves only C as a function of E, the de-icing effectiveness. The determination of C, therefore, was the actual laboratory problem.

EXPERIMENTAL TECHNIQUES

An ordinary petri dish, 3.5 in. in diameter and 0.55 in. in height, was used as the ice-containing receptacle. A pouring spout was notched on the upper portion of the dish.

The testing method was as follows:

A petri dish, into which 10 ml of water had been placed, was stored in a low-temperature cabinet at 0 F [illegible]. The time of storage [illegible] that the [illegible]

CARL BERGER, Ice Physics Project Supervisor, Commonwealth Engineering Co. of Ohio, Dayton, has been working on a program in ice physics with reference to nucleation and crystallization of supercooled water, and the adhesion of ice and the development of an effective de-icing spray.

Authorized Reprint from the Copyrighted ASTM BULLETIN No. [illegible], April, 1954

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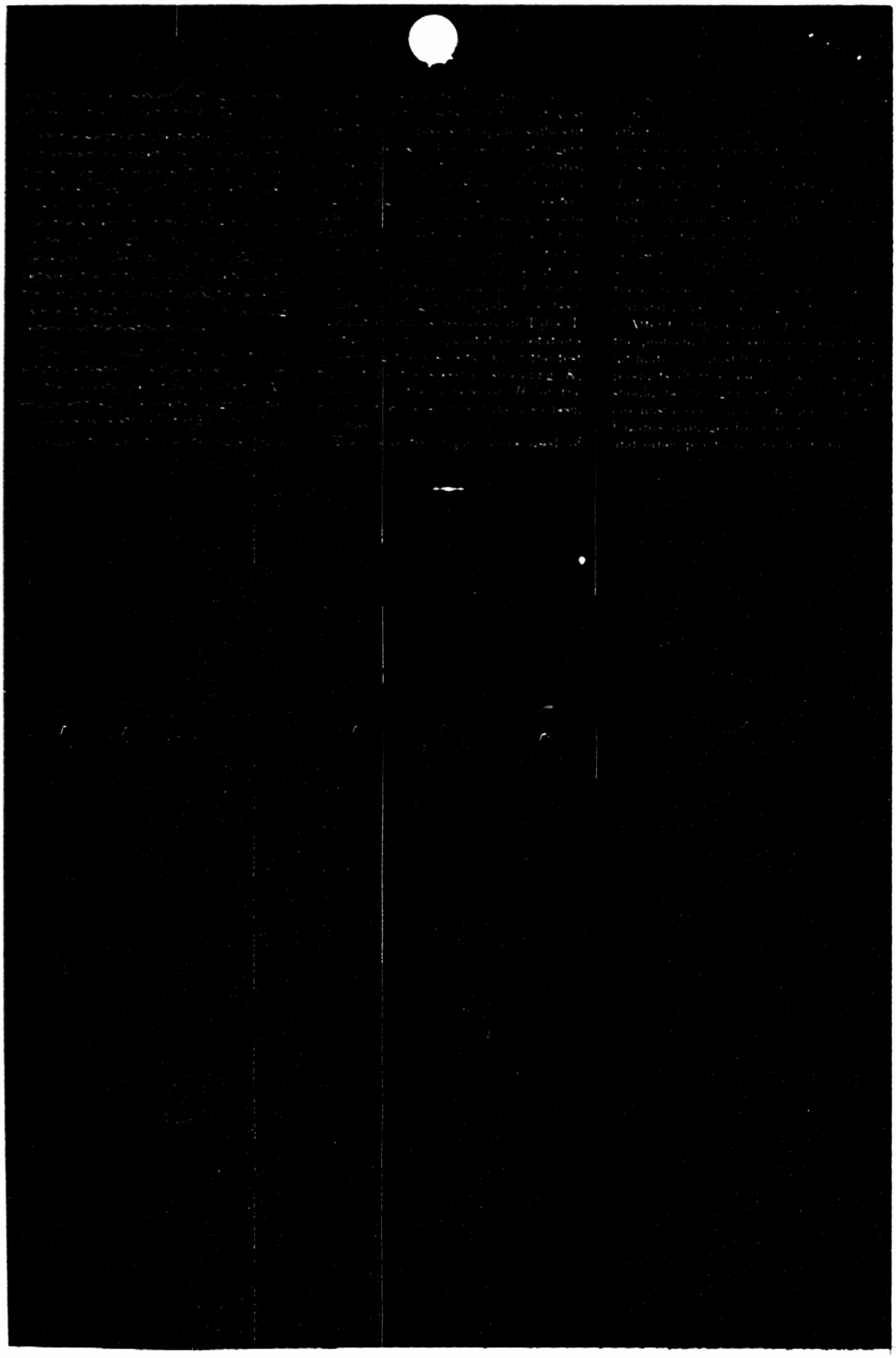

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DEPARTMENT OF COMMERCE
United States Patent Office
Washington

Paper No. 9

Mailed November 28, 1956. Pat. Div. 43

Applicant: Carl Berger
Ser. No. 370,533
Filed July 27, 1953

For RECONSTITUTION OF FROZEN BIOLOGICAL CELLULAR MATERIAL

Toulmin & Toulmin
308 West First Street
Dayton, Ohio

Please find below a communication from the EXAMINER in charge of this application.

/s/ Robert C. Watson
Commissioner of Patents

Responsive to proposed amendment of October 31, 1956.

The amendment submitted October 31, 1956 has been carefully considered, but has not been entered.

Claim 25 can not be entered since the limitation "freed of oxygen and filled with inert gas" is without basis in the specification.

If the amendment to page 8 of the specification and claims 24 and 26 were presented in an amendment, divorced from claim 25, they could be entered for purposes of appeal.

The claims stand rejected for lack of utility in the absence of a showing that applicant's method of using high temperatures to thaw blood cells does not cause denaturation of the blood cells. It is well known in the art that heat denatures blood to render it unfit for transfusion purposes. Applicant has made no showing, in the specification or otherwise, to the effect that his thawed blood composition is suitable for transfusion.

A proper response to the Final rejection of May 28, 1956 is required in order to avoid the issue of abandonment.

/s/ D. Arnold
Examiner

SRosen:lwl

IN THE UNITED STATES PATENT OFFICE

Division 43

In re application of
CARL BERGER
Serial No. 370,533
Filed July 27, 1953

For: RECONSTITUTION OF FROZEN BIOLOGICAL CELLULAR MATERIAL

APPEAL TO THE BOARD OF APPEALS

Honorable Commissioner of Patents
Washington, D. C.

Sir:

Applicant hereby appeals to the Board of Appeals from the decision of the principal examiner finally rejecting Claims 3, 6, 9, 10, 12, 14, 15 and 17.

Entry of Claims 24, 25 and 26 is also requested for purposes of appeal.

The appeal fee of $25 is presented herewith.

Respectfully submitted,

Toulmin & Toulmin

By /s/ Harry A. Toulmin, Jr.

Washington, D. C.
November 28, 1956

IN THE UNITED STATES PATENT OFFICE

Division 43

In re application of
CARL BERGER
Serial No. 370,533
Filed July 27, 1953

For: RECONSTITUTION OF FROZEN BIOLOGICAL CELLULAR MATERIAL

Honorable Commissioner of Patents
Washington, D. C.

Sir:

In re the above-entitled application, entry of Claims 24, 25 and 26 submitted in our amendment filed October 31, 1956 is requested for purposes of appeal.

Respectfully submitted,

Toulmin & Toulmin

By /s/ Harry A. Toulmin, Jr.

Washington, D. C.
November 28, 1956

IN THE UNITED STATES PATENT OFFICE

In re application of
CARL BERGER
Serial No. 370,533
Filed July 27, 1953

For: RECONSTITUTION OF FROZEN BIOLOGICAL CELLULAR MATERIAL

ON APPEAL

Honorable Commissioner of Patents
Washington, D. C.

Sir:

In case the above entitled application has already been forwarded to the Board of Appeals, it is respectfully requested that the application be returned to Division 43 in view of amendment being filed of even date.

Respectfully submitted.

Toulmin & Toulmin

By /s/ Harry A. Toulmin, Jr.

Washington, D. C.
December 4, 1956

IN THE UNITED STATES PATENT OFFICE

Division 43

In re application of
CARL BERGER
Serial No. 370.533
Filed July 27, 1953

For: RECONSTITUTION OF FROZEN BIOLOGICAL CELLULAR MATERIAL

AFFIDAVIT

I, HARRY A. TOULMIN, JR., being duly sworn state as follows—

THAT the assignee of the above-entitled application, of which the undersigned is Chairman of the Board, has been engaged in the field of blood and blood substitutes for a number of years;

THAT it has done the research work, engineering, and designing of a multi-million dollar plant for the production of blood substitutes, in the course of which extensive studies of the problems of producing and reconstituting frozen biological cellular materials have been examined and have been the subject of extensive experimentation;

THAT in connection with the blood work we have worked extensively with the Blood Group under the administration of Dr. Margaret Sloan, of the National Research Council;

THAT Dr. Sloan submitted to the writer the problem of how to so treat whole blood in order to preserve it and so as to be able to rapidly reconstitute it without injury to the red blood cells;

THAT upon having this important problem outlined to the writer I immediately consulted with Dr. Carl Berger of The Commonwealth Engineering Company of Ohio Research Laboratories, in the Division of that company dealing with matters of this character;

THAT attached hereto is a reprint from "Science" of October 30, 1953, of work of Dr. Berger in the field of freezing while an employee of The Commonwealth Engineering Company of Ohio under a grant of the United States Air Force;

THAT Dr. Berger from this experience in connection with so-called beta ice and his long experimentation in that research program which cost the Government of the United States $50,000, arrived at the solution of the present application upon my submitting to him the desire of the National Research Council to get a solution to the aforementioned problem which is set forth in the specification of the above-entitled application;

THAT this has been, according to the advices of Dr. Sloan, one of the most critical problems in the whole blood program, both in the Armed Forces and for the Civilian Agencies;

THAT the utility of this development is due to the fact that you can get a very fast process for reconstitution of the frozen blood cells without injury to the cells;

THAT this injury is very difficult to prevent and Dr. Berger was able to succeed, utilizing the process of the claims in this application;

THAT we are advised by Dr. Sloan that this contribution, if we could make a solution of the problem, would be a substantial contribution both to National Defense and to the Medical Arts;

THAT The Commonwealth Engineering Company of Ohio, therefore, proceeded as a matter of public interest, to explore the problem and solve it, and did so at its own expense because of its confidence in the representations of Dr. Sloan as to the utility of any results that would be secured if we were successful in developing the process;

THAT in the judgment of the writer and his associate executives, and the experts in this field at The Commonwealth Engineering Company of Ohio, this contribution is practical, useful, and solves a problem that our investigation shows has long remained unsolved, and does so in a way that is quick, cheap and effective.

/s/ Harry A. Toulmin, Jr.

DISTRICT OF COLUMBIA)
CITY OF WASHINGTON) ss

Subscribed and sworn to before me a Notary Public this 28 day of November 1956.

SEAL /s/ Helen D. Gutman
Notary Public

My commission expires February 28, 1956.

Reprinted from Science, October [illegible]

The Existence of "Beta" Ice

Carl Berger and Charles M. Saffer, Jr.

*The Commonwealth Engineering Company of Ohio,
1771 Springfield St., Dayton, Ohio*

Seljakov (*1–3*) has reported the existence of a low temperature modification of ordinary ice (ice I) prepared at atmospheric pressure, which he has termed "beta" ice to distinguish it from normal hexagonal or "alpha" ice. He reported that beta ice gave a Laue pattern with rhombohedral symmetry different from the sixfold symmetry of the hexagonal Laue pattern of ordinary ice. The beta ice pattern was observed with crystals grown from water at temperatures (ambient air) in the range −5 to −16 °C. Seljakov further assumed that a strong (0002) reflection characterized the beta structure and that beta ice was transformed into the alpha structure on grinding.

The existence of this beta ice form has not been confirmed by subsequent workers. It is, however, frequently referred to in the literature as a distinct crystal form.[1] During the course of an ice physics investigation conducted for the U.S. Air Force,[2] we were led to consider the validity of Seljakov's conclusions as part of a laboratory investigation of nucleation and crystallization of supercooled water.

It was difficult to follow Seljakov's experimental procedure in detail as it was not explicitly described. Following his procedures as closely as possible, however, it was found that ice crystals appeared at water temperatures of approximately −2.5 to −3° C, when the ambient air temperature varied between −5 and −16° C. The water was kept in a metal pan and temperature measurements were made with a thermocouple immersed in the supercooled water.

These experiments cast considerable doubt on the assumption implicit in Seljakov's reports that the ambient air temperature is equivalent to, or an indication of, the temperature to which the supercooled water was cooled before freezing occurred. Further, Seljakov has not observed a critical temperature [illegible] which beta ice is never found. Thus beta ice was observed (*3*) (once out of 3 trials) when water was frozen at an ambient air temperature of only [illegible]. Seljakov also reported the presence of beta ice on the surface of lake water.

In a review article (*4*) Owston has noted that Seljakov did not make efforts to test for preferred orientation in his powder specimens, the probable [illegible] the absence of the (0002) reflection on [illegible] graphs, and that he took only one rotation photograph. Further, in an earlier paper Owston and Lonsdale [illegible] noted that "It is possible to get an apparently pseudotrigonal Laue picture from ordinary hexagonal ice when it is tilted by a few degrees from the hexagonal axis."

At our request Dr. Barbara W. Low [illegible] examined ice crystals grown at an ambient air temperature of −15° C. Her x-ray crystallographic studies confirm and elaborate those of Owston and Lonsdale; a single crystal gave a pseudotrigonal Laue pattern when tilted so that the sixfold axis made an angle of approximately 15° with the x-ray beam. Ordinary ice I (alpha) gives a pseudotrigonal pattern in this position because of the numerical relationship between the lengths of the *a* and *c* axes. The Laue pattern arises from two equivalent and one nonequivalent zones. The Seljakov pattern (*3*) itself shows this same feature—two identical and one dissimilar ellipses. The characteristic beta Laue pattern of ice, therefore, may be obtained from ordinary alpha ice when it is tilted in the manner described.

On the basis of these studies and observations we conclude that there is no evidence to support the existence of a beta form of ice.

References

1. Seljakov, N. [illegible] 10 (1936).
2. [illegible] *Ibid.* **11**, [illegible]
3. [illegible] *Ibid.* **14**, [illegible] (1937).
4. Owston, P. G., *Quart. Rev.* [illegible]
5. Owston, P. G. and Lonsdale, K., [illegible]
6. Low, B. W., Personal communication.

Manuscript received [illegible]

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[1] See, for example, *Handbook of Chemistry and Physics* ([illegible]nd ed., p. 2225; New York: Chemical Rubber Pub., 1950-51).

[2] U.S. Air Force Contract AF [illegible] 1958.

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DEPARTMENT OF COMMERCE
United States Patent Office
Washington

Paper No. 12

Mailed December 17, 1956. Pat. Div. 43

Applicant: Carl Berger
Ser. No. 370,533
Filed July 27, 1953

For RECONSTITUTION OF FROZEN BIOLOGICAL CELLULAR MATERIAL

Toulmin & Toulmin
308 West First Street
Dayton, Ohio

Please find below a communication from the EXAMINER in charge of this application.

/s/ Robert C. Watson
Commissioner of Patents

Claims 17 and 24 to 26 are the only claims remaining in this application.

The amendments submitted October 3, 1956, October 31, 1956 and December 4, 1956 have all been entered.

The only issue remaining in this case is the rejection for lack of utility. The affidavit submitted December 4, 1956 has been carefully considered, but is not considered convincing to the Examiner. This affidavit contains nothing more than back-ground information and conclusions as to the utility of the process. No where in the affidavit is there a positive showing to the effect that rapidly thawed blood obtained by the process of this invention is not affected (denatured) by the high temperatures of the process and that the rapidly thawed blood produces a result comparable to that produced by slowly thawed blood when injected into a living person. Therefore the claims stand rejected for lack of utility.

No claim is allowed.

The Examiner awaits applicant's appeal brief.

/s/ D. Arnold
Examiner

SRosen: lwl

solutions. And finally the cells are exposed to an arbitrarily selected temperature from 4 to 6°C (about 40°F), well below the point at which the body would perish of cold. The degree and rate of these changes varies considerably, depending on the composition of the preservative solution and temperature.

It might be argued that prolonged preservation of red cells was dependent on the maintenance of morphological and functional integrity during storage. However, to date, no means of preventing the changes described above, during storage, have yet been found. But the degree and rate of these changes can be measured. The question is how far these changes can be permitted to proceed before the red cell as a functioning unit has been destroyed. At the present time there is only one way by which the question can be answered, in the case of a particular blood, and that is by direct measurement of the number of cells which remain in circulation after being infused into the blood stream of a human recipient.

Measurements of Viability

There are at present two established methods of determining post-transfusion survival of red cells. One is the so-called agglutination method developed by Ashby (13), based on the known immunological properties of the four major types of red cells. In practice, a known quantity of cells from a group O donor are transfused into a group A recipient. Samples of the recipient's blood are withdrawn, and with technical precautions, the A cells are agglutinated with anti-A typing serum and the number of O cells of the donor, which are not agglutinated by the serum, are counted as the basis of the percentage of the total O cells given still remaining in the recipient's blood stream. By this method the test cells can be followed until all have disappeared from the blood stream.

The other method consists of "tagging" the red cells of a donor with radioiron, accomplished by the intravenous injection of a tracer dose of the isotope (14). Since this radioiron is incorporated into the hemoglobin molecule, it does not leak out of the intact cell. A quantity of such tagged cells are transfused into the recipient and the percentage of such cells remaining in the recipient's blood stream is calculated from the measured level of radioactivity in a sample of the recipient's cells. The technique is

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SPECIAL INSTRUCTIONS Nat S.L.
TITLE Tullis - Blood Cells and Plasma Proteins
VOL. PAGES Academic Press, NYC

used for the measurement of immediate survival only, since, if many cells are destroyed, the reutilization of radioiron from broken-down cells masks the true disappearance curve of the transfused cells. Either one of these two methods gives data which may serve as a yardstick for the evaluation of changes observed *in vitro* as to the suitability for transfusion of cells stored in a given solution. A great deal of work has been done in attempting to correlate observed physical and chemical changes with post-transfusion survival of those same cells.

Preservation of Red Cells: The Effect of Citrate, Dextrose, and pH

Besides temperature, the major variables that have been experimented with in preservative solutions are citrate and dextrose content and hydrogen ion concentration, determined mainly by the buffering action of sodium citrate and citric acid. In discussing these variables, we shall draw largely on the reported works of Rapoport (15-18), Parpart (19, 20), Denstedt (21), Strumia (22-24), Ross (25), and my own group at Harvard Medical School and Massachusetts Institute of Technology, who collaborated on preservation studies during World War II, under contract with the OSRD (26-29).

For purposes of simplicity, we will confine ourselves to results obtained with 3 types of solution: (1) sodium citrate, without added dextrose; (2) sodium citrate with added dextrose; and (3) sodium citrate plus citric acid and dextrose. The first two solutions are slightly alkaline: pH 7.1-7.4, the last quite acid, pH 5.5. The exact formulas of these solutions or the proportion of diluent to whole blood are not important at this time.

Survival studies of red cells drawn as whole blood into these three solutions showed interesting and important differences. For physiological and clinical reasons beyond the scope of this paper, a satisfactory and safe transfusion of stored blood may be considered as one in which not less than 70 per cent of the transfused cells remain in reasonable functional state in the recipient's blood stream. Based on this figure we can speak of a "dating period," or the period of storage beyond which a blood cannot be safely transfused. If a series of bloods are drawn into a given solution, put into storage on the same day and transfused at intervals, the data obtained permit evaluating the efficiency of the solution. In the case of sodium citrate alone, the dating period did not exceed four days. When dextrose was added, the

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IN THE UNITED STATES PATENT OFFICE

ON APPEAL

In re application of
CARL BERGER
Serial No. 370,533
Filed July 27, 1953

For: RECONSTITUTION OF FROZEN BIOLOGICAL CELLULAR MATERIAL

AFFIDAVIT

I, LEO J. NOVAK being duly sworn, depose and state—

THAT I am Vice-President in charge of Research and Development for The Commonwealth Engineering Company of Ohio;

THAT I am acquainted with the above entitled invention and method of reconstituting frozen biological blood cells in accordance with applicant's invention;

THAT the process for reconstituting frozen blood cells consists in passing the same through an enclosure having a temperature gradient from the entrance to the exit as set forth in the claims and produces a reconstituted blood cell product which when collected in an isotonic liquid can be used in like manner as frozen blood cells which have been slowly heated up to approximately 37°C in the conventional manner;

THAT frozen blood cells reconstituted in accordance with applicant's invention have been used and found to be satisfactory.

/s/ Leo Novak

STATE OF OHIO)
COUNTY OF MONTGOMERY) SS

Subscribed and sworn to before me a Notary Public this 21st day of December, 1956.

/s/ Aileen W. Thompson
Notary Public

SEAL

IN THE UNITED STATES PATENT OFFICE

APPEAL NO. 5969

In re application of
CARL BERGER
Serial No. 370,533
Filed July 27, 1953

For: RECONSTITUTION OF FROZEN BIOLOGICAL CELLULAR MATERIAL

Honorable Commissioner of Patents
Washington, D. C.

Sir:

APPLICANT'S BRIEF

Applicant, through his counsel, appeals from the Final Rejection of Claims 17, 24, 25 and 26, the only claims remaining in the application.

THE CLAIMS

The claims on appeal are—

17. A process for the reconstitution of frozen blood cells which includes the steps of establishing a temperature gradient channel decreasing substantially uniformly between 250°C and 50°C, flowing a stream of the cells under the influence of gravity alone through said temperature gradient channel being initially subjected to said temperature of 250°C to substantially thaw the cells in a time on the order of seconds, and collecting the cells after passing through said temperature gradient channel in an isotonic solution having substantially the same temperature as the thawed cells.

24. A process for the reconstitution of frozen blood cells which consists in passing the same through an enclosure having a temperature gradient from the entrance to the exit of between 1100°C and 250°C at said entrance and 37°C to 50°C at said exit, the temperature decreasing substantially

uniformly therebetween, said blood cells entering and passing through said temperature gradient enclosure within approximately one to two seconds to thaw the same quickly, and thereafter collecting the resultant thawed cells in an isotonic liquid having substantially the same temperature as the thawed cells.

25. A process for the reconstitution of frozen blood cells which consists in propelling the same through an enclosure with inert gas, said enclosure having a temperature gradient from the entrance to the exit of between 1100°C and 250°C at said entrance and 37°C to 50°C at said exit, the temperature decreasing substantially uniformly therebetween, said blood cells entering and passing through said temperature gradient enclosure within a few seconds to thaw the same quickly, and thereafter collecting the resultant thawed cells in an isotonic liquid having substantially the same temperature as the thawed cells.

26. A process for the reconstitution of frozen blood cells which tend to cluster, said process comprising flowing the same through a heat gradient atmosphere which starts initially at a temperature of approximately 1100°C and decreases substantially uniformly to a temperature of approximately 37°C, said cells being passed through said gradient atmosphere at a high rate of speed and on the order of from one to two seconds, and wherein a velocity is imparted to said cells by inert gas introduced into said gradient atmosphere, and collecting said blood cells after passing through said gradient atmosphere in an isotonic liquid, said liquid being at substantially the same temperature as the cells after passing through said gradient atmosphere.

THE INVENTION

The invention relates to a new process for reconstituting frozen blood cells whereby the cells are conditioned for immediate use. Previous methods used for the reconstitution of frozen blood cells are very slow and, in general, require that the frozen blood cells be gradually heated in slow stages until the material has reached the desired temperature of about 37°C.

Applicant has devised a novel method for rapid reconstitution of frozen biological materials such as frozen blood cells which consists in passing the frozen material through an elongated tube surrounded by a heating coil with a funnel means at the lower end which communicates with a container partially filled with an isotonic solution into which the material is received after passing through the heated tube. The heated tube has a temperature of approximately 1100°C at its entrance end and decreases substantially uniformly to a temperature of approximately 37°C at its discharge end.

In carrying out the process, the material to be reconstituted may be simply dropped through the heated tube and into the isotonic solution, the tube being filled with inert gas to act as a carrier or suspension media for the frozen material. In treating frozen blood in accordance with applicant's invention, by passing the same through the differentially heated tube, heat rapidly penetrates the outer cell wall surrounding the central nucleus and freeing the cells for individual motion so that the cells are separated and heated uniformly from all sides whereby the same is quickly reconstituted and ready for use.

REJECTION

The claims stand rejected solely on the ground of lack of utility.

In answer to this ground of rejection applicant filed two affidavits as follows—

(1) Harry A. Toulmin, Jr., which set out the problem confronted by Dr. Berger and its importance, and confirmed that applicant at length had found a solution to

the problem by the process of the present application. Affiant further stated that the process of applicant constituted a practical solution to the problem and that the method is quick, cheap and effective.

(2) An affidavit of Dr. Leo J. Novak, Vice-President in charge of Research and Development for The Commonwealth Engineering Company of Ohio was submitted wherein affiant averred that frozen blood cells reconstituted in accordance with applicant's process have been used and found to be satisfactory.

In the light of applicant's specification and the affidavits aforementioned, it is submitted that the rejection of the claims for lack of utility is untenable and their allowance approved.

Support for counsel for applicant's position is found in the decision of Ex parte Kesel 103 USPQ 103—where the Board of Appeals in a similar case in which a rejection was based upon the ground of lack of utility urged by the Examiner, stated in overruling this rejection—

> "A claim covering a known composition of recognized utility and a new ingredient added thereto, in our opinion, may not be rejected on the ground of lack of utility because it is not conclusively proved that the added ingredient enhances the properties of the old composition, so long as the added ingredient does not destroy the recognized utility of the composition and the composition is capable of performing the function ascribed thereto in the specification."

The case referred to was concerned with a dentifrice and where strict proof is required of allegations made in the specification relative to its utility.

Further, in a still later case the Court of Customs and Patent Appeals held in In re Reiners vs. Mehltretter 111 USPQ 97, that it was not necessary in order to establish utility to show that a product can be used immediately without further change to perform a useful function. As the Court rightly pointed out, a product may be useful as a starting or intermediate material.

In view of the foregoing it is believed applicant has fully overcome the Examiner's rejection and that applicant is accordingly entitled to the allowance of the claims.

Respectfully submitted.

TOULMIN & TOULMIN

By /s/ Harry A. Toulmin, Jr.

Washington, D. C.
January 25, 1957

DEPARTMENT OF COMMERCE
United States Patent Office
Washington

Appeal No. 59-69

Before the Board of Appeals

In re application of Carl Berger
Ser. No. 370,533
Filed July 27, 1953

For RECONSTITUTION OF FROZEN BIOLOGICAL CELLULAR MATERIAL

Toulmin and Toulmin
for Appellant

EXAMINER'S ANSWER

This is an appeal from the final rejection of claims 17 and 24-26.

A correct copy of the appealed claims appears on pages 1 and 2 of applicant's brief.

Reference cited to show the state of the art:

Tullis—Blood Cells and Plasma Proteins, 1953
Academic Press, NYC, pp. 207 and 208

Tullis is cited to show the type of tests which should have been presented to establish utility in a case of this nature.

The alleged invention is adequately described on pages 3 and 4 of applicant's brief.

The only issue remaining in this case is the rejection for lack of utility.

Claims 17 and 24-26 stand rejected for lack of utility. Since blood is extremely labile, the Examiner has questioned the operativeness of applicant's process wherein blood is subjected to extremely high temperatures. The Examiner is of the opinion that high temperatures denature blood thus making it unfit for transfusion purposes. In order to rebut the position taken by the Examiner, applicant has presented two affidavits (see papers Nos. 11 and 13). These affidavits are nothing more than opinion affidavits in that they set forth nothing more than conclusions. Tests on the order suggested by Tullis, cited to show the state of the art, should have been presented as a showing of utility. In the absence of tests establishing the utility of applicant's process the rejection for lack of utility is considered proper.

Applicant has cited Ex parte Kesel 103 U.S.P.Q. 103 to support his position. The Examiner is of the opinion however, that this decision is not pertinent to the facts of this case. Applicant is not adding another ingredient to a composition of known utility, but is subjecting whole blood to very high temperatures which are liable to denature the blood, thus rendering it ineffective for transfusion purposes.

For the reasons set forth the rejections are sound and should be affirmed.

Respectfully submitted,

/s/ (illegible)
Acting Examiner, Div. 43

S.Rosen : lwl

Toulmin and Toulmin
308 W. First St.
Dayton, Ohio

IN THE UNITED STATES PATENT OFFICE

Appeal No. 59-69

In re application of
CARL BERGER
Serial No. 370,533
Filed July 27, 1953

For: RECONSTITUTION OF FROZEN BIOLOGICAL CELLULAR MATERIAL

Honorable Commissioner of Patents
Washington, D. C.

Sir:

APPLICANT'S REPLY BRIEF

The Examiner asserts there is no showing made of utility and that he believes the process would denature the blood.

It is submitted that this grounds for rejecting the claims has been overcome by the affidavits of record of (1) Harry A. Toulmin, Jr. (November 28, 1956) and (2) that of Dr. Leo J. Novak.

In the affidavit of Harry A. Toulmin, Jr. the affiant states that the assignee of the instant patent application has conducted extended research work in the production of blood substitutes and in the course of which extensive studies of the problems of producing and reconstituting frozen biological cellular materials were made.

The affiant further pointed out that the inventor of the process of this patent application was Dr. Carl Berger who has been a research worker in the field of low temperature treatment and its affects, reference being made to a published article by applicant in "Science" of October 30, 1953.

In the affidavit of Dr. Leo J. Novak (December 21, 1956) affiant stated that the process for reconstituting frozen blood cells in accordance with applicant (Dr. Berger's) invention, which was developed under his general supervision, provided reconstituted blood which could be used in like manner as frozen blood cells which had been slowly heated up to 37°C.

Affiant further averred that frozen blood cells reconstituted in accordance with applicant's invention have been used and found to be satisfactory.

The Courts approve affidavits of the character here as reiterated in In re McKenna et al (decided April 15, 1953 USPQ 203 F(2) 717; 674 O.G. 9). There the Court pointed out that exparte affidavits were proper and one of the few practical methods of presenting a factual record, and that the same may be properly used, particularly when made by a party or parties other than the applicant.

It is accordingly believed that applicant has complied with the requirements of the Patent Law and has shown the process to possess utility which is the only grounds given for rejecting applicant's claims.

Respectfully submitted,

Toulmin & Toulmin

By /s/ Harry A. Toulmin, Jr.

Washington, D. C.
March 27, 1957

Mailed May 6, 1959, U. S. Patent Office

Board of Appeals

IN THE UNITED STATES PATENT OFFICE

Paper No. 17

Appeal No. 59-69

BEFORE THE BOARD OF APPEALS

Ex parte Carl Berger

Application for Patent filed July 27, 1953. Serial No. 370,533. Reconstitution of Frozen Biological Cellular Material.

Toulmin and Toulmin for appellant.

Before Asp and Surle, Examiners-in-Chief, and Wiles, Acting Examiner-in-Chief.

Asp, Examiner-in-Chief.

This is an appeal from the final rejection of claims 3, 6, 9, 10, 12, 14, 15, 17, 24, 25 and 26. Subsequent to the notice of appeal an amendment was filed cancelling claims 3, 6, 9, 10, 12, 14 and 15, therefore the appeal as to these claims will be dismissed. Claims 17, 24, 25 and 26 are before us for consideration. No claims have been allowed.

Claim 24 is representative and reads:

> **24. A process for the reconstitution of frozen blood cells which consists in passing the same through an enclosure having a temperature gradient from the entrance to the exit of between 1100°C and 250°C at said entrance and 37°C to 50°C at said exit, the temperature decreasing substantially uniformly therebetween, said blood cells entering and passing through said temperature gradient enclosure within approximately one to two seconds to thaw the same quickly,**

and thereafter collecting the resultant thawed cells in an isotonic liquid having substantially the same temperature as the thawed cells.

The reference relied upon is:

Tullis—Blood Cells and Plasma Proteins, 1953, Academic Press, NYC, pp. 207-208

The appealed claims are for a rapid method of thawing frozen blood by subjecting it to a rather high temperature for a short time. The copied claim sufficiently illustrates the procedure.

Claims 17, 24, 25 and 26 have been rejected for lack of utility. The examiner has questioned the operativeness of the process because blood is extremely labile and would therefore be expected to be denatured at these high temperatures. Tullis was cited to show the type of tests which should have been presented to establish utility in a case of this sort.

Appellant has not submitted any factual evidence to establish that frozen blood when rapidly thawed by the claimed process gives a composition useful for transfusion. He relies upon an affidavit by Harry A. Toulmin, Jr. which merely gives the background of the work done by the present applicant and the need for a rapid process. The last paragraph of this affidavit states that in the judgment of the writer this is a practical, useful contribution which solves a problem.

An affidavit by Leo J. Novak alleges that the process produces reconstituted blood which can be used in a manner similar to frozen blood which has been slowly thawed in conventional manner. Affiant also asserts that these products "have been used and found to be satisfactory." If the assertions by Novak are true, it remains unexplained why some clinical evidence has not been submitted in substantiation. Further, since this process is alleged to solve a long standing problem, it would seem logical to conclude that it should have made an impression upon the art and received recognition in the medical profession. No evidence to this effect is of record.

The affidavits in question are by parties in interest (officials of the assignee company) and in effect simply opinion affidavits which in accordance with well established principles are inadequate to establish patentability. See *In re Pike* 1950 C.D. 105, 37 CCPA 795; 178 F. (2d) 949, 84 USPQ 235, 633 OG 680, *In re Pierce* 1930 C.D. 34, 390 O.G. 265, 35 F. (2d) 781, and *In re Kokatnur et al.* 30 CCPA 1025; 1943 C.D. 436; 554 O.G. 6; 135 F. (2d) 933.

The examiner has given sound scientific reasons for rejecting the claims for a lack of utility or inoperativeness for the intended purpose. Appellant has not shown wherein the examiner is in error and has thus far failed to prove his case. As pointed out by the Court in *Isenstead* v. *Watson*, 115 USPQ 408, 157 F. Supp. 7, the Patent Office is warranted in carefully scrutinizing applications for medical patents and in requiring proof of utility.

The *Ex parte Kesel*, 103 USPQ 103 decision cited by appellant in his brief is of no pertinence to the state of facts in this appeal. In *Ex parte Kesel* the applicant for patent was merely adding another ingredient to a dentrifice. In the instant application whole blood is subjected to conditions which would be expected to denature the same and make it unsuitable for transfusion.

The reply brief cites *In re McKenna et al.* 97 USPQ 348; 203 F. (2d) 717; 674 OG 9, on the point that *ex parte* affidavits may properly be submitted and constitute one of the few practical methods of presenting a factual record for application of the "history of the art test." There is no dispute on the state of the art here. The Court further indicated such affidavits should be closely scrutinized. There is nothing in the decision which infers that weight should be given to opinion affidavits. The law on this is still as set forth in the decisions we have cited above.

The appeal as to claims 3, 6, 9, 10, 12, 14 and 15 is dismissed.

The decision of the examiner is affirmed.

BOARD OF APPEALS

/s/ N. A. Asp
Examiner-in-Chief

/s/ T. Surle
Examiner-in-Chief

/s/ William T. Wiles
Examiner-in-Chief
(Acting)

May 6, 1959

Toulmin and Toulmin
308 West First Street
Dayton, Ohio

IN THE UNITED STATES PATENT OFFICE

APPEAL NO. 59-69

In re application of
CARL BERGER
Serial No. 370,533
Filed July 27, 1953

For: RECONSTITUTION OF FROZEN BIOLOGICAL CELLULAR MATERIAL

Honorable Commissioner of Patents
Washington, D. C.

Sir:

REQUEST FOR RECONSIDERATION

Applicant respectfully requests the Honorable Board of Appeals to reconsider their decision in the above entitled application for the following reasons.

In the decision of the Honorable Board of Appeals it is stated that applicant has not submitted any factual evidence to establish that frozen blood when rapidly thawed by applicant's process provides a composition useful for transfusion purposes. Applicant respectfully submits that the record provides ample evidence of this. We point to the affidavit of Leo J. Novak who is an outstanding inventor in this art himself and who directed the development of this invention in the laboratories of The Commonwealth Engineering Company of Ohio.

Further the affiant Leo J. Novak states

> "That the process for reconstituting frozen blood cells consists in passing the same through an enclosure having a temperature gradiant from the entrance to the exit as set forth in the claims and produces a reconstituted blood cell product which

> when collected in an isotonic liquid can be used in like manner as frozen blood cells which have been slowly heated up to approximately 37°C in the conventional manner:
>
> That frozen blood cells reconstituted in accordance with applicant's invention have been used and found to be satisfactory."

The latter paragraph as set out by the affiant states that such reconstituted frozen blood cells *have been used and found to be satisfactory.*

We further point out that applicant here is also an inventor and holds the Degree of Doctor of Philosophy. Further, as referred to in the affidavit of Harry A. Toulmin, Jr., applicant, Carl Berger, has been working in the field of freezing and has published articles on his work and as referred to in said affidavit, by the reprint from "Science" of October 30, 1953.

It is accordingly believed that applicant here has satisfied the requirements of the Patent Office and in view of the fact that it is admitted that there is no art which anticipates applicant's process, it is manifestly unwarranted to deny applicant patent protection for his process when the evidence presented is clearly in his favor and justifies the issuance of a patent under the Rules of the Patent Office.

Moreover the criticism of the affidavit of Harry A. Toulmin, Jr. is unjustified since the affiant points out the problem presented and how it was solved by applicant. Such affidavits have always been recognized as important notwithstanding they may be made by those who have an interest.

In this connection, applicant respectfully refers to the recent decision of the Court of Customs and Patent Appeals in In re Altmann et Bureau decided December 2, 1958, 121 USPQ 262. In that case and wherein a method of deinking waste paper was claimed, the Court said in regard to affidavits—

> "There are of record affidavits filed in connection with a petition to make appellants' application special in the Patent Office. Those affidavits show that the claimed process herein has been extensively tested with satisfactory results, and that, if a patent is granted, appellants' assignee is prepared to build a plant for carrying out the process on a large scale.
>
> On the other hand, the record contains a copy of a letter by A. E. Johnson, Sales Manager of the Curlator Corporation which, as stated by the Examiner, is the assignee of the patent to Hill. The Curlator corresponds closely to the disclosure of that patent and Johnson's letter states that its use is not recommended for deinking. As properly noted by the Examiner and the Board, this letter does not establish that the process defined by Hill is inoperative for deinking, but it does afford a clear indication that no commercial use of the process for that purpose has been made.
>
> Similarly, there is of record an affidavit by appellant, Bureau, to the effect that he made an investigation but was unable to discover that the Moeller process had ever been used commercially."

As will be observed, the Court held such affidavits by even interested parties, were appropriate to show that the claimed process has utility. Furthermore, the Court held that when the claims were limited to the particular combination of steps which produce the improved result, and in view of the affidavits and record shown, that doubts under the authorities are to be resolved in favor of applicant, citing In re Pappas et al, 38 CCPA 746, 185 F2d. 695, 88 USPQ 108; In re Hummer, 44 CCPA 814, 241 F.2d 742, 113 USPQ 66.

The instant case is clearly on all fours with the decisions of the Court of Customs and Patent Appeals and it is believed that the Board upon reconsideration will find applicant entitled to the allowance of the claims.

In regard to the affidavits, the Board of Appeals cites a number of decisions which hold that mere opinion affidavits are inadequate. The affidavits of Novak, taken together with the affidavit of Toulmin and that of the applicant himself, making the application, provides a showing which is adequate and does not fall in the category of simple opinion affidavits. Therefore, it is not seen wherein the decisions therein cited in support thereof are pertinent to applicant's claims.

It is further pointed out that in the decision of the Court of Customs and Patent Appeals of In re McKenna, Redman et al 97 USPQ 348, the Court said in regard to affidavits

> We think also that an affidavit by an applicant or co-applicant as to the advantages of his invention is less persuasive than one made by a disinterested party (see Ex parte Coleman 29 USPQ 378 Board of Appeals). However, this is not to be disregarded for that reason alone and may be relied on when sufficiently convincing. See In re Holt 34 CCPA 1129 and In re Mock 28 CCPA 919, and wherein the CCPA relied on such affidavits in reversing the Board of Appeals.

In addition, in the same decision, McKenna et al supra, the Court of Customs and Patent Appeals said that where the prior art did not suggest the existence of the problem or show how it was solved, as is certainly the case here, applicant was entitled to be given the benefit of his disclosed process, and further that the fact that elements of the process may be found in various patents does not necessarily negative invention, citing In re Holt supra. The Court held that the affirmation by the Board of Appeals of the Examiner was unwarranted in view of the showing made by the applicant, and which included ex parte affidavits as proof, similarly as in the present case.

Further, in regard to the decision of In re Instead vs. Watson 115 USPQ 408 cited, there the Court indicated that the affidavits should be carefully scrutinized but they did not state that affidavits of applicant and interested parties should be disregarded as appears to be the case here, at least as so indicated in the decision.

Similarly in the case of Ex parte Kesel 103 USPQ 103, there the application and claims were concerned with a dentrifrice and which is not at all related to applicant's invention. Here we have a process and new composition. Moreover, the claims are all restricted to a process for reconstituting frozen blood cells employing certain coordinated steps and wherein the temperature of treatment is set forth. Thus, it is not seen wherein the case of Ex parte Kesel is at all pertinent to the case here.

In reference to the decision of In re McKenna supra, the Board states that this is concerned with the history of the art test. This, however, is not so restricted because, as we pointed out above, the decision clearly indicates that affidavits by either applicant or co-applicants, or those who may have an interest, cannot be disregarded and we believe that when carefully reconsidered, it will be found that they do contain sufficient evidence for supporting applicant's contention that he has satisfied the law with respect to disclosing factual evidence of the utility of his invention.

Reconsideration and allowance of the claims on appeal is respectfully solicited.

Respectfully submitted,

TOULMIN & TOULMIN

Washington, D. C.
May 27, 1959

IN THE UNITED STATES PATENT OFFICE

APPEAL NO. 59-69

In re application of
CARL BERGER
Serial No. 370.533
Filed July 27, 1953

For: RECONSTITUTION OF FROZEN BIOLOGICAL CELLULAR MATERIAL

Honorable Commissioner of Patents
Washington, D. C.

Sir:

SUPPLEMENTING APPLICANT'S REQUEST FOR RECONSIDERATION

Further, with reference to the question of commercial recognition raised by the Board of Appeals in their decision, applicant desires to point out that at least one pharmaceutical party has indicated an interest in the process of the invention, and provided patent protection can be obtained, applicant expects to license the invention.

Applicant further submits the following pertinent disclosures in the literature, and which shows that it is conventional to store blood or blood plasma cells at low temperature and later use it for transfusion purposes (note in this connection the following)—

Science News Letter for October 11, 1958—Page 229

"Use Frozen Blood"

"The reporting scientists processed the blood in a fractionator, added glycerol and froze it and stored at -80° to -120°C, the blood was then thawed and deglyceralized in wash solution. . . . .

They said the recovered blood appeared therapeutically comparable to the blood now used for transfusion. . . ."

Also

Science News Letter for September 1956
Vol 124 No. 3221

"Mechanics of Freezing in Living Cells and Tissues—Harold T. Merryman—Page 250

"Thawing following rapid freezing, has been shown to be a very demanding procedure.

The use of means of thawing other than simple conduction have been explored.

It is estimated that, for blood, one second is certainly the upper limit for the total duration of thawing and with this technique the problem of timing to thaw a specimen in one second without boiling it in the ensuing millisecond would be nearly insoluble, even assuming that all portions completed thawing at exactly the same instant. The successful development of a technique other than simple heat exchange by conduction would probably extend considerably both the size and species range amenable to rapid freezing."

As pointed out by the author Dr. Merryman in the Science article above, a solution to the problem of devising a method of thawing frozen blood plasma was needed. Thus prior to applicant (Berger) inventive method of reconstituting frozen blood cells no suitable method had been discovered.

Respectfully submitted

Toulmin & Toulmin

Washington, D. C.
June 18, 1959

Mailed September 24, 1959, U. S. Patent Office
Board of Appeals

IN THE UNITED STATES PATENT OFFICE

Paper No. 20

Appeal No. 59-69

BEFORE THE BOARD OF APPEALS

Ex parte Carl Berger

Application for Patent filed July 27, 1953. Serial No. 370,533. Reconstitution of Frozen Biological Cellular Material.

Toulmin and Toulmin for appellant.

Before Asp and Surle, Examiners-in-Chief, and Wiles, Acting Examiner-in-Chief.

Asp, Examiner-in-Chief.

ON PETITION FOR RECONSIDERATION

A request for reconsideration of our decision of May 6, 1959, has been presented. It is essentially a reiteration of the merits of the affidavits of record which we considered and found insufficient to establish any utility in the claimed process. The reargument is not persuasive of any error in our evaluation of this showing. We remain of the opinion that it does not qualify as factual evidence.

The decisions cited in the petition are not seen to be in point here. In the *Altmann et al.* case, 121 USPQ 262, there was no rejection for lack of utility. The affidavits therein were concerned with commercial aspects for purposes of resolving doubts in favor of patentability.

The supplemental comments filed June 18, 1959 will not be considered because they were not received within the 30 day limit set in Rule 197 for such papers.

The petition has been considered but is denied in respect to making any change in our decision.

BOARD OF APPEALS

/s/ N. A. Asp
Examiner-in-Chief

/s/ T. Surle
Examiner-in-Chief

/s/ William T. Wiles
Examiner-in-Chief
(Acting)

Toulmin and Toulmin
308 West First Street
Dayton, Ohio

United States Court of Appeals

FOR THE DISTRICT OF COLUMBIA CIRCUIT

No. 16,862

THE COMMONWEALTH ENGINEERING COMPANY OF
OHIO and CARL BERGER,
Appellants

vs.

DAVID L. LADD,
COMMISSIONER OF PATENTS

**Appeal from the United States District Court
for the District of Columbia**

BRIEF FOR APPELLANTS

United States Court of Appeals
for the District of Columbia Circuit

FILED MAR 26 1962

Joseph W. Stewart
CLERK

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STATEMENT OF QUESTIONS

The questions presented are as follows:—

(1) Has appellant satisfied the requirement of 35 United States Code 101 with respect to the usefulness of his invention.

(2) Is it necessary, in order to overcome a conclusion expressed by the Patent Office that appellant's process will not operate as claimed, to submit proof other than an expert's *a priori* opinion.

(3) Where only a *process* is claimed as an invention and the process manifestly performs the function described is appellant required to show specific utility of the final product treated by the process of the invention.

INDEX

PAGE

STATEMENT OF QUESTIONS I

TABLE OF CASES III

JURISDICTIONAL STATEMENT 1

STATEMENT OF THE CASE 1

Carl Berger Application 370,533 2

THE CLAIMS 2

STATUTES, REGULATIONS AND RULES INVOLVED 6

STATEMENT OF POINTS 6

SUMMARY OF ARGUMENT 7

ARGUMENT 8

CONCLUSION 13

CITATIONS

Cases:

Isenstead vs. Watson, 157 Fed. Suppl. 7 ...... 5, 7, 10, 11
*Thomas vs. Michael, 166 F(2) 944 (CCPA 1948).. 10
*In re Nelson, 280 F(2) 178 11
*In re McKenna et al, 97 USPQ 348 .... 11, 12
Ex parte Coleman, 29 USPQ 378, Board Appeals 12
*In re Altmann et Bureau, 121 USPQ 262 12

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*Cases chiefly relied upon by appellant.

United States Court of Appeals

FOR THE DISTRICT OF COLUMBIA CIRCUIT

No. 16,862

THE COMMONWEALTH ENGINEERING COMPANY OF
OHIO and CARL BERGER,
Appellants

vs.

DAVID L. LADD,
COMMISSIONER OF PATENTS

Appeal from the United States District Court for the District of Columbia

BRIEF FOR APPELLANTS

JURISDICTIONAL STATEMENT

Jurisdiction over this action was conferred on the District Court for the District of Columbia by 35 U.S.C. p. 145 (Section 145 of the Patent Code), which authorizes a civil action to obtain a patent.

This Court has jurisdiction upon appeal to review the judgment of the District Court by virtue of 28 U.S.C. p. 1291.

STATEMENT OF THE CASE

This action originated in the District Court under Section 145 of the Patent Code (35 U.S.C. p. 145) to authorize the United States Commissioner of Patents to issue a patent with respect to Carl Berger, application Ser.No. 370.533, filed July 27, 1953. The application was entitled "Reconstitution of Frozen Biological Cellular Material". The application and any Letters Patent which might issue thereon was assigned to The Commonwealth Engineering Company of Ohio.

The facts with respect to the aforementioned patent application are as follows:—

Carl Berger Application 370,533

On July 27, 1953, appellant Carl Berger filed an application for Letters Patent in the United States Patent Office for an invention entitled "Reconstitution of Frozen Biological Cellular Material". That application was designated Ser.No. 370.533, and was fully prosecuted in the Patent Office.

A suitable apparatus for carrying out the process in accordance with the appellant's invention was illustrated by a drawing submitted with the patent application. [JA 95]

After all of the claims of said application were rejected by the Primary Examiner of the United States Patent Office, the appellants took an appeal to the Patent Office Board of Appeals with respect to the following claims remaining in the case. [JA 118-119]

THE CLAIMS

17. **A process for the reconstitution of frozen blood cells which includes the steps of establishing a temperature gradient channel decreasing substantially uniformly between 250°C and 50°C, flowing a stream of the cells under the influence of gravity alone through said temperature gradient channel being initially subjected to said temperature of 250°C to substantially thaw the cells in a time on the order of seconds, and collecting the cells after pass-**

ing through said temperature gradient channel in an isotonic solution having substantially the same temperature as the thawed cells.

24. A process for the reconstitution of frozen blood cells which consists in passing the same through an enclosure having a temperature gradient from the entrance to the exit of between 1100°C and 250°C at said entrance and 37°C to 50°C at said exit, the temperature decreasing substantially uniformly therebetween, said blood cells entering and passing through said temperature gradient enclosure within approximately one to two seconds to thaw the same quickly, and thereafter collecting the resultant thawed cells in an isotonic liquid having substantially the same temperature as the thawed cells.

25. A process for the reconstitution of frozen blood cells which consists in propelling the same through an enclosure with inert gas, said enclosure having a temperature gradient from the entrance to the exit of between 1100°C and 250°C at said entrance and 37°C to 50°C at said exit, the temperature decreasing substantially uniformly therebetween, said blood cells entering and passing through said temperature gradient enclosure within a few seconds to thaw the same quickly, and thereafter collecting the resultant thawed cells in an isotonic liquid having substantially the same temperature as the thawed cells.

26. A process for the reconstittuion of frozen blood cells which tend to cluster, said process comprising flowing the same through a heat gradient atmosphere which starts initially at a temperature of approximately 1100°C and decreases substantially uniformly to a temperature of approximately 37°C, said cells being passed through said gradient atmosphere at a high rate of speed and on the order of from one to two seconds, and wherein a velocity is imparted to said cells by inert gas introduced into said gradient atmosphere, and collecting said blood cells after passing through said gradient atmosphere in an isotonic liquid, said liquid being at substantially the same temperature as the cells after passing through said gradient atmosphere.

The Patent Examiner finally rejected all of appellant's claims in the patent application for lack of utility, and asserting there had been no showing made to the effect that the high temperatures that appellant uses would not cause denaturation of the blood proteins due to localized heating. [JA 99]

In response to the Examiner's final rejection of the claims of appellant for lack of utility, substitute claims were submitted along with an affidavit of Harry A. Toulmin. [JA 109-110]

The affidavit of Harry A. Toulmin pointed out the usefulness of appellant's process for quickly reconstituting frozen blood cells without injury to the cells, and to the consultation had by the inventor Dr. Berger with Dr. Sloan of the National Research Council.

The Patent Examiner responded to appellant's amendment and affidavit of Harry A. Toulmin as follows: [JA 113]

> "The only issue remaining in this case is the rejection for lack of utility. The affidavit [Toulmin] submitted December 4, 1956 has been carefully considered, but is not considered convincing to the Examiner. * * * No where in the affidavit is there a positive showing to the effect that rapidly thawed blood by the process of this invention is not affected (denatured) by the high temperature of the process and that the rapidly thawed blood produces a result comparable to that produced by slowly thawed blood when injected into a living person. Therefore, the claims stand rejected for lack of utility."

In response to this continued rejection of the claims because of insufficient showing of utility, appellant filed an affidavit of Dr. Leo J. Novak [JA 117]. The affiant, a P.H.D. and Vice-President in charge of Research and Development for The Commonwealth Engineering Company of Ohio, averred as follows—

> "THAT the process for reconstituting frozen blood cells consists in passing the same through an enclosure having a temperature gradient from the entrance to the exit as set forth in the claims and produces a reconstituted blood cell product which when collected in an isotonic liquid can be used in like manner as frozen blood cells which have been slowly heated up to approximately 37°C in the conventional manner.
>
> THAT frozen blood cells reconstituted in accordance with applicant's invention have been used and found to be satisfactory.

Notwithstanding this additional evidence as to utility of appellant's process by one other than the inventor and an expert in the art, the Examiner refused to allow the application. An appeal was taken to the Board of Appeals.

The Board of Appeals of the Patent Office in a decision dated May 6, 1959 affirmed the Examiner. The Board referring to the affidavits submitted by appellant as "simply opinion affidavits" and made by parties in interest. They further held that appellant had not submitted any factual evidence to establish that frozen blood when rapidly thawed by the claimed process gives a composition useful for transfusion.

Upon appellant's petition for reconsideration by the Board of Appeals they declined to change their affirmation of the Examiner. Appeal was then taken to the District Court for the District of Columbia under 35 U.S.C. p. 145, to authorize the Commissioner of Patents to issue a patent to appellant.

The District Court below disregarded the testimony of appellant's expert Dr. Klotz and dismissed the complaint holding that the evidence presented relative to utility of appellant's invention was of no value for supporting a showing of utility. The Court relied upon its earlier opinion in Isenstead vs. Watson, 157 Fed. Suppl. 7. The appellants believe the record will show that the findings of the District Court below are not well taken and are reversible.

STATUTES, REGULATIONS AND RULES INVOLVED

35 U.S.C. p. 100(b) Definitions

> "The term 'process' means process, art or method, and includes a new use of a known process, machine, manufacture, composition of matter, or material."

35 U.S.C. p. 101 Inventions patentable

> "Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title."

35 U.S.C. p. 112 Specifications

> "The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention.
>
> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention."

STATEMENT OF POINTS

1. The Court below was unwarranted in holding that appellant had not submitted sufficient evidence to establish the utility of his invention.

2. The Court below erred in holding that appellant had not submitted any factual evidence to establish that frozen blood when rapidly thawed by the claimed process gives a composition useful for any purpose whatsoever.

3. The Court below erred in holding that the evidence presented by way of affidavits and appellants' expert witness Dr. Klotz was of no value as evidence for supporting applicant's showing of utility of appellants' invention.

4. It was error for the Court below to hold that appellant was required to show by laboratory experiments that appellant's process will operate as claimed.

5. The Court below was unwarranted in holding that the earlier decision in Isenstead vs. Watson, 157 Suppl. 7, was equally applicable to appellants' case.

6. The Court below erred in failing to consider that appellant's invention is restricted to a *process* rather than a product.

SUMMARY OF ARGUMENT

1. The utility of the process as well as the product treated by the process has been sufficiently proved by the evidence submitted during proceedings in the Patent Office and including affidavits of Harry A. Toulmin and Dr. Leo J. Novak, and as corroborated by appellant's witness Dr. Klotz during the proceeding before the Court below.

2. The process manifestly has utility for rapidly thawing frozen material, and this is not denied by defendant.

3. A *product* and its *utility* is not involved here because the invention, as set forth in the claims, is *a process*. The claims define the specific steps of the admittedly novel procedure thus the claims satisfy the requirements of the patent statute. [35 U.S.C. 112]

ARGUMENT

Utility of the Process has been Proved

The sole ground by the U.S. Patent Office for refusing to grant applicant a patent was that of lack of utility. No questions of anticipation or lack of invention were raised or are here in contention before this Appellate Court.

The record shows that in response to the Patent Examiner's request for additional evidence of usefulness of appellant's invention, an affidavit of Harry A. Toulmin was submitted [JA 109-110].

The affiant includes in his affidavit the following—

> THAT Dr. Berger from this experience in connection with so-called beta ice and his long experimentation in that research program which cost the Government of the United States $50,000, arrived at the solution of the present application upon my submitting to him the desire of the National Research Council to get a solution to the aforementioned problem which is set forth in the specification of the above-entitled application;
>
> THAT the utility of this development is due to the fact that you can get a very fast process for reconstitution of the frozen blood cells without injury to the cells;
>
> THAT this injury is very difficult to prevent and Dr. Berger was able to succeed, utilizing the process of the claims in this application.

Further, after continued rejection of the claims by the Patent Office Examiner appellant filed an affidavit of Dr. Leo J. Novak [JA 117]. In the affidavit the affiant stated as follows—

> "THAT frozen blood cells reconstituted in accordance with applicant's invention *have been used and found to be satisfactory.*" (Emphasis ours)

Further during the proceedings below, appellant presented an expert witness, Dr. Klotz, who testified that the invention had utility and further that the process was one which could be carried out in the laboratory and would be helpful to have in a hospital laboratory for treating sheep blood in frozen form. [Tr—JA 44-45]

It was additionally established by the witness [JA 45] that ordinary storage of sheep blood results in deterioration of the same within periods of two weeks or less, and that it is necessary to reconstitute the supply of such blood in order to carry out laboratory tests.

Dr. Klotz, the witness, also stated that the process would thaw frozen blood without destroying its function and biological properties. The witness testified as follows [Tr—JA 45]

> Q Dr. Klotz, having read the file wrapper of this application, did you observe anything in the proposed process, as to application of heat and adjustments of the variables of time and length of exposure, which would be contrary to recognized scientific principles? A I don't think so, sir.
>
> Q In your opinion, if the length of time of exposure to high temperature is sufficiently small, is it possible to pass red blood cells through a high temperature without scorching them? A I see no reason why not. I would certainly think so.

Also the witness testified relative to the utility of appellant's invention as follows: [Tr—JA 48-49]

> Q Dr. Klotz, taking into account the phenomenon of heat of fusion or latent heat, to which you earlier testified, if, let us say, blood at zero degrees centigrade in its frozen state were exposed to a high temperature for such a sufficiently small length of time that it had merely liquified and had not begun to rise in temperature, would it make any difference at all how much—what the degree of outside heat which had been applied was? A It certainly would not seem so .

Q Is it possible, applying the principle of heat of fusion again, together with the variables of time of exposure, which we have discussed, to pass blood through, frozen blood, through a temperature gradient of let's say 1100 degrees to 37 degrees, provided your speed adjustment is correct, and have the blood come out the discharge end having never risen above 37 degrees centigrade itself? A It would certainly seem so, based on physical principles.

The Court below relied heavily on its earlier decision in Isenstead vs. Watson (157 F. Supp. 7). Appellant points out, however, that in that case "*a new medical compound*" was claimed. On the contrary, the invention of appellant is *a process* and no new product is claimed.

Appellant believes that the Court below misconstrued the ruling in Isenstead v. Watson supra as covering the utility requirement of appellant's present *process* invention. In the first place, as pointed out above, applicant's invention is concerned with a process of treating frozen blood to quickly thaw the same and produce unfrozen blood. The Court below quoted the decision therein with respect to great care and scrutiny which should be taken, particularly in connection with patent applications covering *medical patents*. No medical patent is involved in appellant's invention, therefore the decision does not apply.

Appellant points to the decision in Thomas vs. Michael, 166 F(2) 944 (CCPA 1948) at pages 946-947 [JA 59] as applicable. The Court in that case held:

> "Where the utility of a new product produced by a novel process is not known or apparent, a test is required to establish reduction to practice of that process. But where the utility of an old product produced by a novel process is known, a test is not required to establish reduction to practice of that process."

It is manifest that appellant's novel process produces an old product—unfrozen blood—accordingly a test is not required to establish reduction to practice of the process.

In the decision of Isenstead v. Watson supra, there the Court indicated that the affidavits should be carefully scrutinized but they did not hold that affidavits of applicant and interested parties should be disregarded as appears to be the case here, since the Court below, as pointed out above, held that the evidence presented was of no value.

Appellant submits the decision in point is In re Nelson 280 F(2) 178, where in the Court of Customs and Patent Appeals held that a high degree of usefulness need not be established, and all that is needed is some degree of usefulness. Appellant clearly has established that the invention has some degree of usefulness.

Appellant's Patent Application Supports Broad Uses of the Invention

The appellants' patent application supports a broad use of thawed blood, and the affidavits of Harry A. Toulmin Jr. and that of Dr. Leo Novak, as well as the expert witness Dr. Klotz, indicates blood thawed in accordance with appellants' process has utility at least for laboratory and testing uses.

It is pertinent in this connection to refer the Court to the decision of the Court of Customs and Patent Appeals in In re McKenna et al 97 USPQ 348, wherein the Court said in regard to affidavits

> "We think also that an affidavit by an applicant or co-applicant as to the advantages of his invention

> is less persuasive than one made by a disinterested party (Ex parte Coleman 29 USPQ 378, Board Appeals). However, it is not to be disregarded for that reason alone and may be relied upon when sufficiently convincing." [JA 134]

The Court below referred to the testimony introduced in behalf of the plaintiff, the appellant here, by Dr. Klotz the expert witness as being impressive. [JA 67]. The witness testified that the process of the invention could be employed both in connection with tests and experiments with human blood and animal blood and such as carried out in laboratories.

Further, the Court below is believed to be wrong in holding that "in order to overcome this conclusion some proof must be submitted and not merely another experts a priori opinion, especially a partisan expert". This is manifestly a logical way for appellant to prove the usefulness of this invention. The decisions by the Court of Customs and Patent Appeals have approved such methods. The decision in In re Altmann et Bureau 121 USPQ 262 [JA 132-133] approves the submission of affidavits for this purpose. Similarly, in In re McKenna 97 USPQ 348 [JA 134] the Court indicated that the testimony of experts and ex parte affidavits may be relied upon by an applicant to establish the advantages of his invention. [JA 134]

Accordingly, appellant's *a priori opinions* should have been accepted by the Court below as proper evidence to prove utility of appellant's invention.

It is submitted that the Patent Office is not charged by Congress with the task of protecting the public against possible misuse of patents. This is a function performed ably by the Food and Drug Administration.

Appellant furthermore wishes to emphasize that he has *not claimed* frozen blood treated by his process to quickly unthaw it may be used directly for *transfusion in humans.*

No where in appellant's patent application specification is such a statement made. The defendant however, has stressed this alleged use [Tr—JA 26] and, we respectfully submit, thus may have misled the Court.

Appellant further points out that evidence of utility *of the process* is manifest from the record and testimony. It is also not denied by defendant that the process of the invention of appellant's will thaw frozen blood. The *process* being admittedly new and not anticipated by the prior art is patentable to appellant.

CONCLUSION

The claims, which are all directed to appellant's *process*, and which are rejected *solely* on the grounds that no utility of the invention has been established, are allowable to appellant.

The Court below was in error in finding that the evidence submitted by appellant in the record and at the trial was insufficient, and accordingly the holding of the Court below should be reversed.

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BRIEF FOR APPELLEE

United States Court of Appeals
FOR THE DISTRICT OF COLUMBIA CIRCUIT

Appeal No. 16,862

THE COMMONWEALTH ENGINEERING COMPANY OF OHIO and CARL BERGER, APPELLANTS

v.

DAVID L. LADD, COMMISSIONER OF PATENTS, APPELLEE

Appeal from the Judgment of the United States District Court for the District of Columbia

CLARENCE W. MOORE,
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J. E. ARMORE,
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United States Court of Appeals
for the District of Columbia Circuit

FILED APR 13 1962

Joseph W. Stewart
CLERK

STATEMENT OF QUESTIONS PRESENTED

In the opinion of the appellee, the questions presented in this appeal are:

1. Whether the findings of the District Court that the claimed process fails to satisfy the utility requirement of 35 United States Code 101, since the appellants have not submitted any factual evidence to establish that frozen blood rapidly thawed by said process gives a composition useful for any purpose whatsoever, are so clearly erroneous to warrant their being set aside by this Court in view of Rule 52(a) of the Federal Rules of Civil Procedure and its prior adjudications in this field;

2. Whether the fact that the sole evidence before the trial Court was conflicting a priori opinions on a highly technical and scientific matter permits a holding by this Court that the finding of non-patentability by the District Court lacks substantial basis in the record.

INDEX

Page

Statement of Questions Presented 1

Introduction 1

Appellants' Application 2

The Claims 3

Summary of Argument 3

Argument 4

Conclusion 10

Authorities Cited:

Abbott et al v. *Coe*, 71 App. D. C. 195, 109 F.2d 449 4

Armour & Co. v. *Wilson & Co.*, 168 F. S. 353, 119 USPQ 365 7

Bullard Co. v. *Coe*, 79 U. S. App. D. C. 369, 147 F.2d 568 4

Esso Standard Oil Co. v. *Sun Oil Co.*, 97 U. S. App. D. C. 154, 229 F.2d 37 4

Isenstead v. *Watson*, 157 F. S. 7 6

Kokatnur et al, In re, 30 CCPA 1025, 135 F.2d 933 6

Pierce, In re, 17 CCPA 626, 35 F.2d 781 6

Pike, In re, 37 CCPA 795 6

Reid, In re, 37 CCPA 884, 179 F.2d 998 6

Schaefer v. *Watson*, 109 U. S. App. D. C. 360, 228 F.2d 144 4

Watson v. *Bersworth*, 102 U. S. App. D. C. 187, 251 F. 2d 898 4

Statutes:

35 U. S. C. 101 3

35 U. S. C. 145 1

United States Court of Appeals
FOR THE DISTRICT OF COLUMBIA CIRCUIT

Appeal No. 16,862

THE COMMONWEALTH ENGINEERING COMPANY OF OHIO and CARL BERGER, APPELLANTS

v.

DAVID L. LADD, COMMISSIONER OF PATENTS, APPELLEE

Appeal from the Judgment of the United States District Court for the District of Columbia

INTRODUCTION

This is an appeal from the judgment (J.A.-84) of the United States District Court for the District of Columbia dismissing the complaint in an action brought under 35 U.S.C. 145. In that action, the appellants, constituting the corporate assignee and applicant Carl Berger, of application Serial No. 370,533, filed July 27, 1953, entitled "Reconstitution of Frozen Biological Cellular Material", sought to have that Court authorize the issuance of a patent to them containing certain designated claims in the application.

The complaint was dismissed by the trial Court after a hearing at which the appellants introduced expert testimony in an effort to show patentability. The District Court rendered an oral opinion (J.A.-74 to 79), followed by findings of fact and conclusions of law (J.A.-80 to 83), sustaining appellee's refusal to grant the requested patent. Notice of appeal was timely filed on January 11, 1962.

APPELLANTS' APPLICATION

The alleged invention described in the application at bar relates to a process for reconstituting frozen red blood cells by quick heating in a temperature gradient enclosure, in a matter of seconds, and recovering the thawed cells in an isotonic solution (J.A.-87). The process consists of passing the frozen red blood cells through a vertical tube, either by gravity drop or as a suspension in an inert gas such as nitrogen or argon, the tube having a uniform temperature gradient gradually decreasing from 250° C. to 1100° C. at the entrance to from 37° C. to 50° C. at the discharge end, and receiving the thawed blood cells in an isotonic saline solution having the temperature of the thawed cells (J.A. 81 to 90).

According to the specification, previous methods for reconstitution "to render it suitable, for example, for human use have involved the heating of the cells in slow increments" until the desired temperature of 37° C. is attained, but this tends to produce denaturation within the cells due to deterious reactions therein as the temperature rises (J.A.-87). The specification alleges that the extremely rapid activation of the cells inhibits deleterious reactions (J.A.-92) and that the disclosed process conditions the cells for immediate use (J.A.-87).

THE CLAIMS

The four appealed claims 17, 24, 25 and 26 (J.A.-118, 119) are drawn to the process for the reconstitution of frozen blood cells discussed above, the claims varying with respect to temperatures and means for passing the frozen cells through the temperature gradient channel. Claim 24 is generic. All claims stand or fall together.

SUMMARY OF ARGUMENT

1. The appealed claims are unpatentable for the reason that the utility requirement of 35 United States Code 101 has not been satisfied. High temperatures denature blood and the appellants have not submitted any factual evidence to establish that frozen blood cells when rapidly thawed by the claimed process gives a composition useful for any purpose whatsoever. There is no usefulness whatever in any degree where the process will destroy the usefulness and value of the very product intended to be produced by ruining its vital properties. Therefore, the claimed process is entirely lacking in utility.

2. The utility requirement of 35 United States Code 101 would particularly warrant careful scrutiny and proof of utility in connection with applications for medical patents in view of the likely public reliance upon a medical patent as an official certification of its stated results and benefits. This is applicable to all applications for medical patents, whether the

claims are drawn to a product or to a process as in the case at bar. Therefore, since the process of the appealed claims results in a product clearly intended for a medical use and it has not been shown by experimentation that the product will have such usefulness, the claimed process lacks the utility required by 35 United States Code 101.

ARGUMENT

It is respectfully submitted that, in an action to obtain a patent, the basic issue before the Court is whether the finding of non-patentability made by the Patent Office, and concurred in by the District Court, lacks substantial support in the record. This has been the established rule of this Court. *Abbott et al.* v. *Coe,* 71 App. D.C. 195, 109 F.2d 449; *Esso Standard Oil Co.* v. *Sun Oil Co.,* 97 U.S. App. D.C. 154, 229 F.2d 37. Only if the finding of non-patentability is "clearly wrong" does this Court reverse. *Bullard Co.* v. *Coe,* 79 U.S. App. D.C. 369, 147 F.2d 568; *Watson* v. *Bersworth et al.,* 102 U.S. App. D.C. 187, 251 F.2d 898; *Schafer* v. *Watson,* 109 U.S. App. D.C. 360, 288 F.2d 144.

In the present case, the District Court concluded that "the ruling of the Patent Office has not been sufficiently overcome to justify the Court in reaching the conclusion that the Patent Office erred" (J.A.-77). Findings of Fact Nos. 7, 8 and 9 embody that conclusion (J.A.-81, 82). The appellants must show that these findings are "clearly wrong" to prevail.

The issue of this appeal revolves about Finding 7 (J.A.-81) of the trial court that the appellants have not submitted any factual evidence to establish that frozen blood when rapidly thawed by the claimed process gives a composition useful for any purpose whatsoever. Utility is one of the statutory requirements for patentability (35 United States Code 101). The appealed claims were refused by the Patent Office (J.A.-123, 127) as lacking utility since blood is extremely labile which causes it to undergo changes at high temperatures, thus denaturing the blood and rendering it unfit for transfusion purposes. Therefore, in the absence of any factual evidence that frozen blood, when rapidly thawed by the claimed process, gives a composition useful for transfusion or, as added by the trial court in its opinion (J.A.-75), useful for any purpose whatsoever, the process is entirely lacking in utility. The trial court also stated in its opinion that the "specification does not indicate the purpose or purposes for which this process is to be used" (J.A.-74); this statement is embodied in Finding 3 (J.A.-80).

In contending for the patentability of the appealed claims, the appellants assert that the utility of the claimed process has been proved (Br-8). They rely upon the affidavits of Harry A. Toulmin and Dr. Leo J. Novak (Br-8), as well as the testimony of Dr. Klotz (Br-9, 10). An inspection of the Toulmin affidavit (J.A.-109 to 111), including the excerpt thereof in the appellants' brief (Br-8), indicates that the affidavit merely states that the process is a fast method for reconstitution of the frozen blood cells without injury to the cells. The Novak affidavit (J.A.-117) merely states that frozen blood cells reconstituted in accordance with the claimed process have been used and found to be satisfactory. The testimony of the witness, Dr. Klotz, including the portion excerpted in the appellants' brief (Br-9, 10), amounts to no more than a tentative opinion that frozen blood may be rapidly thawed at high temperature without damage "provided your speed adjustment is correct" (Br-10). The affidavits and testimony are no more than expressions of opinion and the District Court properly concluded that the appellants have not submitted any factual evidence to establish that frozen blood when rapidly thawed by the claimed process gives a composition useful for any purpose whatsoever (J.A.-75). It may further be noted that the affidavits and testimony were from interested sources since they issued from officials of the corporate appellant. Also, it is well established that patentability cannot be predicated upon opinion affidavits unsupported by factual evidence; *In re Pike*, 37 CCPA 795, 178 F.2d 949; *In re Reid*, 37 CCPA 884, 179 F.2d 998; *In re Kokatnur et al.*, 30 CCPA 1025, 135 F.2d 933; and *In re Pierce*, 17 CCPA 626, 35 F.2d 781. Therefore, Findings 7, 8 and 9 have substantial support in the record and are not clearly erroneous.

The utility requirement of the statute in 35 United States Code 101 has particular significance in an application involving a medical utilization as in the case at bar. In considering such application in a previous decision in *Isenstead* v. *Watson*, 157 F.Supp. 7, the trial court has stated that:

> "Great care and scrutiny should be particularly taken in connection with applications for medical patents. While the granting of a patent does not legally constitute a certificate that the medicine to which it relates is a good medicine and will cure the disease or successfully make the test which it was intended to do, nevertheless, the granting of such a patent gives a kind of official imprimatur to the medicine in question on which as a moral matter some members of the public are likely to rely. In view of these circumstances, it is right and proper that the Patent Office should be very careful and perhaps even reluctant to grant a patent on a new medical formula until it has been thoroughly tested and successfully tried by more than one physician."

The trial court quoted a portion of the above decision in its opinion in the case at bar (J.A.-79). The decision in *Isenstead* v. *Watson*, *supra*, was followed in *Armour and Co.* v. *Wilson and Co.*, U. S. District Court, N.D. Illinois, E.D., 168 F.Supp. 353, 363, 119 USPQ 365. It is submitted that, in view of the considerations set forth in the above quotation from the decision in *Isenstead* v. *Watson*, the failure of the appellants to supply factual evidence of utility takes on an added significance and clearly renders the appealed claims unpatentable for failing to meet the statutory requirement of utility. The appellants' argument that the case at bar may be distinguished from *Isenstead* v. *Watson* in that the latter case claimed "a new medical compound" while the appealed claims are drawn to a process (Br-10) is without substance since both cases involve medical applications and therefore the principles enunciated in the previous decision are equally applicable to both cases. The holding to this effect by the trial court in its opinion (J.A.-79) and Conclusion of Law 10 (J.A.-83) are therefore not clearly erroneous.

The appellants imply that the trial court disregarded the Toulmin and Novak affidavits as those of interested parties since it "held that the evidence presented was of no value" (Br-11). They further cite the decisions of the Court of Customs and Patent Appeals in In re McKenna and In re Altmann et al., as indicating that such affidavits may be relied upon when sufficiently convincing (Br-11, 12). However, it is quite clear that the District Court did not disregard the affidavits or, for that matter, the testimony of Dr. Klotz, but rather found that no factual evidence had been submitted to establish that the claimed process resulted in a useful product. (Finding 7—J.A.-81) and it is submitted that this finding is clearly correct. This finding of the District Court is not in conflict with the decisions cited by the appellants.

The appellants rely on the decision in Thomas v. Michael, (Br-10) as holding that tests are not required when an old product is produced by a new process and the cecision in In re Nelson (Br-11) for the rule that a high degree of usefulness need not be established. There is no dispute with the law as expressed in the decisions cited of the appellants but those decisions are not applicable to the case at bar. In the present case, as stated in Finding (7 J.A.-81), there is no factual evidence that the claimed process results in a product useful for any purpose whatsoever despite the fact that the Patent Office had pointed out that high temperatures normally denature blood and normally make it unfit for transfusion purposes. (J.A.-128). While a high degree of utility may not be necessary under the statute no factual evidence was presented herein to contravert the Patent Office holding that the process will destroy the very product it is designed to produce and, therefore, as held if the trial court (J.A.-76) "* * * on that basis, the process is entirely lacking in utility".

Finally, the appellants argue that their application supports a broad use for thawed blood, with testimony showing utility at least for laboratory and testing uses (Br-11); that the Patent Office is not charged with protecting the public against misuse of patenta; and that the specification and claims are not limited for direct transfusion in humans (Br-12, 13). These arguments cannot be persuasive of clear error, or any error in Findings 7, 8 and 9 of the trial court (J.A.-81, 82). The testimony constituted merely a priori opinion evidence, without any factual basis, and therefore cannot successfully rebut the refusal of the appealed claims by the Patent Office on the ground that high temperatures denature blood and therefore the product of the appealed claims can have no utility. The absence of any factual evidence that the claimed process results in a product having any utility whatsoever renders the process entirely lacking in utility and the appealed claims unpatentable in view of the utility requirement in 35 United States Code 101. The argument relative to protection of the public by the Patent Office against patent mis-

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CONCLUSION

All the claims on appeal, it is submitted, were properly refused to the appellants on the ground that the process claimed therein lacks utility. Accordingly, it is further submitted that the judgment appealed from was correct and should be affirmed.

Respectfully submitted,

C. W. MOORE
Solicitor United States Patent Office
Attorney for Appellee.

J. E. ARMORE,
Of Counsel

UNITED STATES COURT OF APPEALS
DISTRICT OF COLUMBIA CIRCUIT

Appeal No. 16,862

THE COMMONWEALTH ENGINEERING COMPANY OF OHIO and CARL BERGER, APPELLANTS

v.

DAVID L. LADD, COMMISSIONER OF PATENTS, APPELLEE

CERTIFICATE UNDER RULE 18(d)

Submitted herewith is one typewritten copy of the brief for the appellee. A further copy thereof has today been placed in the hands of the printer. No changes in the brief to be filed in printed form will be made, except for minor changes or correction. The required number of copies of the printed brief will be filed within ten days.

Respectfully submitted,

/s/ C. W. Moore
Solicitor, U. S. Patent Office,
Attorney for Appellee

April 5, 1962

REPLY BRIEF FOR APPELLANTS

United States Court of Appeals
FOR THE DISTRICT OF COLUMBIA CIRCUIT

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and CARL BERGER,
Appellants

v.

DAVID L. LADD, COMMISSIONER OF PATENTS,
Appellee

Appeal from the Judgment of the United States District Court for the District of Columbia

United States Court of Appeals
for the District of Columbia Circuit

FILED APR 27 1962

Joseph W. Stewart
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REPLY BRIEF FOR APPELLANTS

APPELLANTS HAVE ESTABLISHED UTILITY FOR THE PROCESS

The usefulness of appellants' process is clearly set forth in the original patent application and this is corroborated by appellants expert witness during the trial by the Court below. In regard to the showing of usefulness, the Court's attention is respectfully directed to the disclosure in appellants original patent application [J.A. p. 87 etc]. Therein the primary *object* and *use* of the *process* is set out as follows: [J.A. p. 87]

> "It is accordingly a primary object of the invention to describe a novel method for the rapid reconstitution of frozen biological cellular material.

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> "It is accordingly a primary object of the invention to describe a novel method for the rapid reconstitution of frozen biological cellular material.

> It is a particular object of this invention to describe a novel method for the reconstitution of frozen red blood cells.
>
> It is a further object of this invention to describe a method for the reconstitution of frozen red blood cells which method conditions the cells for immediate use."

Further, in the application specification appellant describes the utility and limitations for properly carrying out his process. This is set out as follows [J.A. o. 91]—

> "The extremely rapid activation of the cells (as low as a matter of a second or two) which inhibits deleterious reactions within the cell, the simplicity of the inexpensive apparatus required, *the utility of the method and apparatus for various types of particles*, the ability to maintain particle temperature always below that of the desired end temperature in tube traverse, and the uniformity of heating of the particles in the tube itself are prime factors in the inventive concept." (emphasis added).
>
> "Where a velocity is imparted to the cells and an inert gas is employed to carry the same the temperature gradient may be as high as 1000°C, that is 1100°C at the entrance and about 37°C at the exit of the tube. The only limitation between time and temperature in this connection is that the velocity be sufficiently high to prevent scorching of the cells."

The original disclosure thus clearly sets out the objects and utility of appellant's process.

It will also be noted that nowhere in the original patent application is there *any* reference made to using the product produced by appellant's process for human transfusion. This has been stressed and emphasized by counsel for appellee throughout the trial below and in his brief [Appellee's brief, pg. 5 and 8; J. A. pg. 30, 31].

The Court's attention is respectfully directed to the statement of counsel for appellee [J.A. p. 43, 44]—as follows—

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Respectfully submitted,

TOULMIN & TOULMIN
Attorneys for Appellants

April 19, 1962

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The Court's attention is respectfully directed to the statement of counsel for appellee [J.A. p. 43, 44]—as follows—

> "Mr. Armore: Your Honor, I object to that line of questioning in view of the fact that the disclosure in the *specification is limited exclusively to human transfusion* and for the reasons that I have indicated before, in view of the decisions I have referred to before in my opening remarks." (Emphasis added).

This is clearly an erroneous statement and it is redundent to counsel for appellee's statement [J.A. p. 26, 1, 16], as follows—

> "there is no evidence in the record showing that the product has any utility."

This repeated reference and emphasis by appellee's counsel that appellant's product, when treated in accordance with his process, is only or primarily useful for blood transfusion purposes is *clearly in error*. This is manifestly introducing *new matter* in appellant's description of his invention. Further, by such emphasis by counsel for appellee the Court below was misled and erroneously relied upon their previous decision in Isenstead v. Watson, 157 F. Supp. 7, as urged by appellee to support his contention that appellant's *product* falls under this decision. [Appellee's brief, pg. 6, 7].

In the first place, as pointed out above, appellants' invention is not a *product*, neither is it a *medical compound or the like product*, as was concerned in the Isenstead v. Watson decision supra.

THE RECORD AND EVIDENCE PRESENTED AT THE HEARING CORROBORATES APELLANTS' PATENT APPLICATION DISCLOSURE

First as regards the record, during pendency of the application in the Patent Office counsel for appellants respectfully direct the Court's attention to the following showings:—

(1) The affidavit of Leo J. Novak, Vice-President in charge of research and development for The

Commonwealth Engineering Company of Ohio [J.A. p. 117].

There affiant averred as follows—

> "That the *process* for reconstituting frozen blood cells consists in passing the same through an enclosure having a temperature gradient from the entrance to the exit as set forth in the claims and produces a reconstituted blood cell product which when collected in an isotonic liquid can be used in like manner as frozen blood cells which have been slowly heated up to approximately 37°C in the conventional manner. That frozen blood cells reconstituted in accordance with applicant's invention have been used and found to be satisfactory." (emphasis ours)

(2) The affidavit of Harry A. Toulmin, Jr. [J.A. p. 109], wherein affiant sets out as follows [J.A. p. 110, 111]—

> "That in the judgment of the writer and his associate executives, and the experts in this field at The Commonwealth Engineering Company of Ohio, this contribution is practical, and solves a problem that our investigation shows has long remained unsolved, and does so in a way that is quick, cheap and effective."

Further, the expert witness Dr. Klotz testified at the trial [J.A. p. 45] in answer to counsel's question, as follows—

Q. In your opinion, as one who has worked in laboratories, would it be helpful to have in a hospital laboratory a supply of sheep blood corpuscles stored in a frozen form.

A. (witness) I would say yes, for the reason that ordinary storage of sheep blood corpuscles results in their deterioration within periods of possibly two weeks or less. Therefore, it is necessary to constantly reconstitute the supply of corpuscles in order to carry out this particular examination."

The Court below further set out as follows [J.A. p. 43]

> THE COURT: I do not understand that the Patent Office questions the fact that you can thaw out frozen blood by your process. What they question is whether the blood that you get by your process is a useful product in the technical sense."
> MR. ARMORE: Yes, your Honor.
> THE COURT: Very well

It is clear from the above that as to the process there was no question that it was not operable to thaw frozen blood or other biological material and such as set out in appellant's patent specification [J.A. p. 87]. It will be noted there that appellant's invention relates to

> "the reconstitution of frozen biological material and particularly to the reconstitution of frozen blood cells"

In addition, reference is made to the subject matter at the end of appellants' patent specification and wherein it is stated [J.A. 92]—

> "This invention is susceptible to modification in order to adopt it to different usages and conditions and accordingly it is desired to comprehend such modifications within this invention as may fall within the scope of the appended claims."

THE COURT AND THE PATENT OFFICE ERRONEOUSLY RELIED UPON THE PREVIOUS DECISION IN ISENSTEAD v. WATSON AS SUPPORTING THEIR DECISION AND OPINION IN THE CASE AT BAR

The decision in Isenstead v. Watson, supra, relied upon by appellee's counsel, and the Court below is inapt because appellant's invention *is not a medical product* as was involved in Isenstead vs. Watson. The Court below failed to take into consideration the *nature of appellant's claims*. They are each true process claims.

The Court below, as well as the Patent Office erroneously followed the Isenstead v. Watson decision, supra, and failed to appreciate that appellant's invention is *not a medical product*. A decision of this Court of Appeals and directly in point is—

> *Montgomery et al* vs. *Marzall Commissioner of Patents 189 F(2) 640.*

There the Court held, in reversing the decision of the Patent Office tribunals and the District Court below, and where *a process* of cast coating paper was in issue, that:—

> "In like manner, the Patent Office tribunals and the District Court have in this case mistaken the *nature of the claims* in issue. *They are true process claims*, in that they describe the acts to be done in manufacturing cast coated paper, including *new steps* added by appellants to the previously practiced process. *The claims are not for the compounding of ingredients into a new product*, nor are they for a *manutured* article, the characteristics of which are caused or affected by the materials of which it is made. That is to say, *these are not claims for compounding a new coating composition* by adding a specified proportion of oil. The coating composition is the same as before." (Emphasis ours).

The Court further pointed out—

> "The arguments [by defense] we think misconceives the nature of the claims in suit. The [claims] *do not state* merely the results to be achieved but are *process claims* which set out a series of steps by which the desired ends are attained with sufficient definiteness to inform persons skilled in the art and to limit the extent of the monopoly of the patent. It was not necessary or practicable for Clayton to specify the exact degree of emulsion breaking temperature or the precise length of time needed for the substantial neutralization of every quantity of oil that might be subjected to refinement;"

and completed, as we are convinced that he did, the first use of D.P.G. as an accelerator in making vulcanized rubber, he does not lose his right to use this discovery when he chooses to do so, for scientific purposes of publication, because he does not subsequently sell the rubber thus vulcanized, or use his discovery in trade, or does not apply for a patent for it. It is not an *abandoned experiment because he confines his use of the rubber thus produced to his laboratory or to his lecture room.*" (Emphasis ours).

CONCLUSION

It is submitted that appellants have shown that the decisions of the Patent Office tribunals and the District Court below are clearly erroneous and the presumption of their correctness has been overcome. Accordingly, it is prayed that this Court will overrule their decision and allow appellants to obtain a patent on their new process.

The Court accordingly held *process claims* to be allowable.

This decision in Montgomery et al vs. Marzall Commissioner of Patents was cited with approval in a recent case by this Court of Appeals in reversing the Patent Office and the District Court, in:—

> *Glass Fibers L.O.F. Co.* vs. *Watson, Commissioner of Patents, 228 Fed(2) 40.*

There, in a case involving the manufacture of glass fibers, this Court reversed the Patent Office tribunals and District Court, citing:—

> Larsen vs. Marzall (1952)
> 90 U.S. App. D.C. 260; 195 F(2) 200
>
> and, referring to
>
> Montgomery vs. Marzall 1951, 88 U.S. Appl.D.C. 281 189 F(2) 640, said:—
>
> "While there is evidence upon which, in part, the findings can be supported, on the entire evidence we are left with the definite and firm conviction that a mistake has been committed. Citing—Dollar vs. Land 1950—87 U.S. App. D.C. 214, 184 F(2) 245 certiorari denied (1950) 340 U.S. 884."

Further, in the Glass Fibers case, supra, the Court said, with respect to their review of the entire record—

> "We are permitted a 'subjective opinion or formulation of a judgment'."

UNITED STATES SUPERME COURT DECISION SUPPORTING APPELLANTS' CASE

Counsel for appellants calls the Honorable Court's attention to the United States Supreme Court decision in Corona Co. vs. Dovan Corp., 276 U.S. Reports, 358, at p. 384. There is a chemical process case, the Court said—

> "It is a mistake to assume that reduction to use must necessarily be a commercial use. If Kratz discovered

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Respectfully submitted,

TOULMIN & TOULMIN
Attorneys for Appellants

April 19, 1962

April 19, 1962

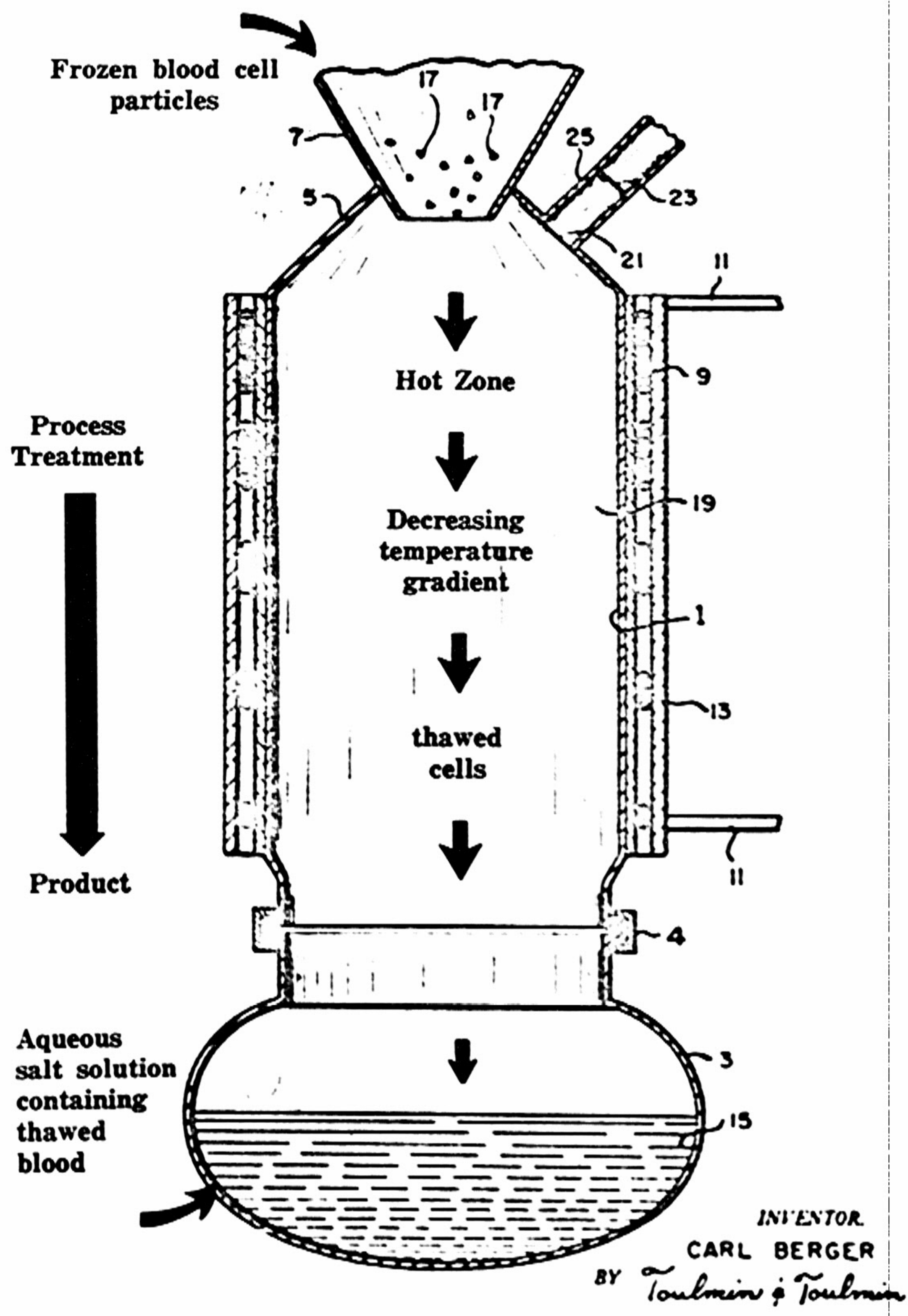
I hereby certify that two copies of the typewritten Reply Brief for appellants and Certificate Under Rule 18(d) were personally served today to the attorney for appelee, C. W. Moore, Solicitor, United States Patent Office, Washington, D. C.

TOULMIN & TOULMIN

By ....

Attorneys for Appellants

APPENDIX


Frozen blood cell particles
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1
thawed cells
13
Product
11
4
Aqueous salt solution containing thawed blood
3
15

INVENTOR
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